

US008864730B2

(12) **United States Patent**  
**Conway et al.**

(10) **Patent No.:** **US 8,864,730 B2**  
(45) **Date of Patent:** **Oct. 21, 2014**

(54) **SILICONE RUBBER MALE EXTERNAL CATHETER WITH ABSORBENT AND ADHESIVE**

USPC ..... 604/349, 346, 347, 351, 352, 540, 544  
See application file for complete search history.

(75) Inventors: **Anthony J. Conway**, Chatfield, MN (US); **Richard D. Fryer, Jr.**, Chatfield, MN (US)

(56) **References Cited**

(73) Assignee: **Rochester Medical Corporation**, Stewartville, MN (US)

U.S. PATENT DOCUMENTS

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 509 days.

480,911 A \* 8/1892 Vance ..... 604/349  
822,092 A \* 5/1906 Woodruff ..... 604/352

(Continued)

(21) Appl. No.: **11/104,388**

FOREIGN PATENT DOCUMENTS

(22) Filed: **Apr. 12, 2005**

CA 763930 7/1967  
DE 352014 4/1922

(Continued)

(65) **Prior Publication Data**  
US 2006/0229576 A1 Oct. 12, 2006

OTHER PUBLICATIONS

“Life, Liberty and the Pursuit of Happiness. Liberty Pouch will set you free!,” BioDerm, Inc., 2 pages (Publicly known prior to the filing date of the present application).

(Continued)

(51) **Int. Cl.**  
*A61F 5/44* (2006.01)  
*A61F 5/453* (2006.01)  
*A61F 13/471* (2006.01)  
*A61F 13/82* (2006.01)  
*A61F 6/04* (2006.01)  
*A61F 6/02* (2006.01)

*Primary Examiner* — Adam Marcetich  
(74) *Attorney, Agent, or Firm* — Rutan & Tucker, LLP

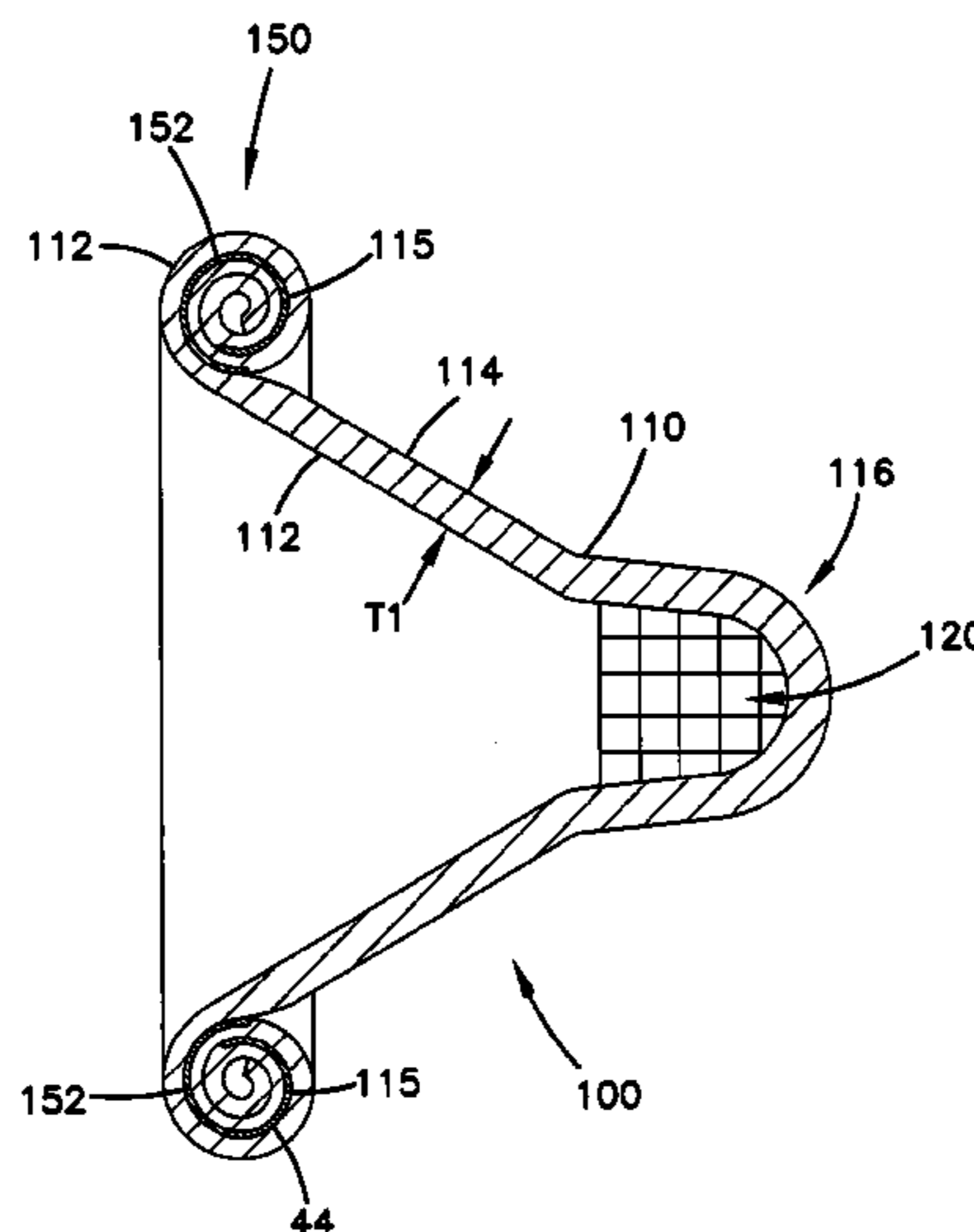
(52) **U.S. Cl.**  
CPC ..... *A61F 5/453* (2013.01); *A61F 2006/044* (2013.01); *A61F 13/471* (2013.01); *A61F 13/82* (2013.01); *A61F 6/04* (2013.01); *A61F 6/02* (2013.01)  
USPC ..... **604/346**; 604/347; 604/349; 604/540; 604/544; 128/844

(57) **ABSTRACT**

The invention relates generally to external urinary catheters for males. More specifically, the invention relates to an external urinary catheter that includes an absorbent material to absorb urinary discharge. The absorbent material can be located in either a distal end of a tubular sheath, or in a receptacle that attached to the distal end of the tubular sheath. The tubular sheath of the external urinary catheter can include a tubular sheath of silicone rubber, wherein the sheath has an inner surface and an outer surface, and a layer of adhesive material directly and non-releasably bonded to the inner surface.

(58) **Field of Classification Search**  
CPC ..... A61F 5/453; A61F 5/451; A61F 5/4404; A61F 5/4405; A61F 5/4407; A61F 5/443; A61F 5/44; A61F 5/48; A61F 2006/044; A61F 2006/047; Y10S 128/918; A61B 10/007

**27 Claims, 9 Drawing Sheets**



(56)

References Cited

U.S. PATENT DOCUMENTS

1,235,142 A	7/1917	Ichilian	3,889,685 A	6/1975	Miller, Jr. et al.
1,643,289 A	8/1927	Peglay	3,894,540 A	7/1975	Bonner, Jr.
1,661,494 A	3/1928	Nielsen	3,898,993 A	8/1975	Taniguchi
2,043,630 A	6/1936	raiche	3,903,893 A	9/1975	Scheer
2,213,210 A	9/1940	Egbert	3,924,634 A	12/1975	Taylor et al.
2,228,992 A	1/1941	Frey	3,926,705 A	12/1975	Todd
2,230,226 A	4/1941	Auzin	3,930,580 A	1/1976	Bazell et al.
2,248,934 A	7/1941	Auzin	3,934,721 A	1/1976	Juster et al.
2,285,502 A	6/1942	Dreyfus	3,962,519 A	6/1976	Rusch et al.
2,308,484 A	1/1943	Auzin et al.	3,967,728 A	7/1976	Gordon et al.
2,314,262 A	3/1943	Winder	3,981,299 A	9/1976	Murray
2,320,157 A	5/1943	Raiche	3,983,879 A	10/1976	Todd
2,322,858 A	6/1943	Limbert et al.	4,026,296 A	5/1977	Stoy et al.
2,330,399 A	9/1943	Widner	4,029,104 A	6/1977	Kerber
2,330,400 A	9/1943	Winder	4,055,682 A	10/1977	Merrill
2,389,831 A	11/1945	Welsh	4,062,363 A	12/1977	Bonner
2,390,070 A	12/1945	Auzin	4,091,922 A	5/1978	Egler
2,481,488 A	9/1949	Auzin	4,119,094 A	10/1978	Micklus et al.
2,494,393 A	1/1950	Lamson	4,120,715 A	10/1978	Ockwell et al.
2,610,626 A	9/1952	Edwards	4,133,303 A	1/1979	Patel
2,638,093 A	5/1953	Kulick	4,140,127 A	2/1979	Cianci et al.
2,649,619 A	8/1953	Killian	4,149,539 A	4/1979	Cianci
2,649,854 A	8/1953	Salm	4,168,699 A	9/1979	Hauser
2,690,595 A	10/1954	Raiche	4,186,745 A	2/1980	Lewis et al.
2,712,161 A	7/1955	Moss	4,187,851 A	2/1980	Hauser
2,856,932 A	10/1958	Griffitts	4,196,731 A	4/1980	Laurin et al.
2,912,981 A	11/1959	Keough	4,198,983 A	4/1980	Becker et al.
3,044,468 A	7/1962	Birtwell	4,198,984 A	4/1980	Taylor
3,053,257 A	9/1962	Birtwell	4,209,010 A	6/1980	Ward et al.
3,076,464 A	2/1963	Rosenburg	4,225,371 A	9/1980	Taylor et al.
3,154,080 A	10/1964	Rowan et al.	4,230,115 A	10/1980	Walz, Jr. et al.
3,169,527 A	2/1965	Sheridan	4,246,909 A	1/1981	Wu et al.
3,211,151 A	10/1965	Foderick et al.	4,249,535 A	2/1981	Hargest, III
3,304,353 A	2/1967	Harautueian	4,252,760 A	2/1981	Foster et al.
3,345,988 A	10/1967	Vitello	4,265,848 A	5/1981	Rüsch
3,394,704 A	7/1968	Dery	4,266,999 A	5/1981	Baler
3,394,705 A	7/1968	Abramson	4,269,310 A	5/1981	Uson
3,403,682 A	10/1968	McDonell	4,284,459 A	8/1981	Patel et al.
3,409,016 A	11/1968	Foley	4,287,227 A	9/1981	Kamada et al.
3,434,869 A	3/1969	Davidson	4,311,146 A	1/1982	Wonder
3,463,141 A	8/1969	Mozolf	4,311,659 A	1/1982	Rey et al.
3,503,400 A	3/1970	Osthagen et al.	4,318,406 A	3/1982	McLeod
3,508,959 A	4/1970	Krahnke	4,318,947 A	3/1982	Joung
3,509,884 A	5/1970	Bell	4,341,817 A	7/1982	Tozier et al.
3,520,305 A	7/1970	Davis	4,342,392 A	8/1982	Cox
3,539,674 A	11/1970	Dereniuk et al.	4,343,788 A	8/1982	Mustacich et al.
3,544,668 A	12/1970	Dereniuk	4,366,901 A	1/1983	Short
3,548,805 A	12/1970	Datsenko	4,367,732 A	1/1983	Poulsen et al.
3,556,294 A	1/1971	Walck, III et al.	4,378,018 A *	3/1983	Alexander et al. .... 604/350
3,566,874 A	3/1971	Shepherd et al.	4,378,796 A	4/1983	Milhaud
3,593,713 A	7/1971	Bogoff et al.	4,379,506 A	4/1983	Davidson
3,598,127 A	8/1971	Wepsic	4,381,008 A	4/1983	Thomas et al.
3,606,889 A	9/1971	Arblaster	4,381,380 A	4/1983	LaVeen et al.
3,642,004 A	2/1972	Osthagen et al.	4,395,806 A	8/1983	Wonder et al.
3,646,929 A	3/1972	Bonnar	4,411,648 A	10/1983	Davis et al.
3,648,704 A	3/1972	Jackson	4,419,097 A	12/1983	Rowland
3,683,928 A	8/1972	Kuntz	4,428,365 A	1/1984	Hakky
3,695,921 A	10/1972	Shepherd et al.	4,446,860 A *	5/1984	Gutnick ..... 128/844
3,699,956 A	10/1972	Kitrilakis et al.	4,457,299 A	7/1984	Cornwell
3,699,964 A	10/1972	Ericson	4,472,226 A	9/1984	Redinger et al.
3,708,324 A	1/1973	Stebleton	4,475,910 A *	10/1984	Conway et al. .... 604/352
3,726,281 A	4/1973	Norton et al.	4,477,325 A	10/1984	Osburn
3,739,783 A	6/1973	Broerman	4,479,795 A	10/1984	Mustacich et al.
3,762,399 A	10/1973	Riedell	4,515,593 A	5/1985	Norton
3,768,102 A	10/1973	Kwan-Gett et al.	4,534,768 A	8/1985	Osburn et al.
3,788,324 A *	1/1974	Lim ..... 604/352	4,539,234 A	9/1985	Sakamoto et al.
3,794,042 A	2/1974	De Klotz et al.	4,540,409 A	9/1985	Nystrom et al.
3,797,478 A	3/1974	Walsh et al.	4,553,533 A	11/1985	Leighton
3,838,728 A	10/1974	Voegel	4,563,184 A	1/1986	Korol
3,841,304 A	10/1974	Jones	4,568,340 A	2/1986	Giacalone
3,854,483 A	12/1974	Powers	4,571,239 A	2/1986	Heyman
3,861,395 A	1/1975	Taniguchi	4,571,240 A	2/1986	Samson et al.
3,875,937 A	4/1975	Schmitt et al.	4,576,599 A *	3/1986	Lipner ..... 604/390
3,879,516 A	4/1975	Wolvek	4,581,026 A	4/1986	Schneider
3,882,220 A	5/1975	Ryder	4,581,028 A	4/1986	Fox, Jr. et al.
			4,582,762 A	4/1986	Onohara et al.
			4,586,974 A	5/1986	Nystrom et al.
			4,589,874 A	5/1986	Riedel et al.
			4,592,920 A	6/1986	Murtfeldt

(56)

References Cited

U.S. PATENT DOCUMENTS

4,597,765 A	7/1986	Klatt	4,932,938 A	6/1990	Goldberg
4,597,931 A	7/1986	Watanabe et al.	4,932,948 A	6/1990	Kernes et al.
4,601,713 A	7/1986	Fuqua	4,934,999 A	6/1990	Bader
4,603,152 A	7/1986	Laurin et al.	4,935,260 A	6/1990	Shlenker
4,612,337 A	9/1986	Fox, Jr. et al.	4,950,256 A	8/1990	Luther et al.
4,613,324 A	9/1986	Ghajar	4,952,618 A	8/1990	Olsen
4,615,692 A	10/1986	Giacalone et al.	4,963,137 A	10/1990	Heyden
4,615,697 A	10/1986	Robinson	4,968,294 A	11/1990	Salama
4,622,033 A	11/1986	Taniguchi	4,968,507 A	11/1990	Zentner et al.
4,623,329 A	11/1986	Drobish et al.	4,976,703 A	12/1990	Franetzki et al.
4,626,250 A	12/1986	Schneider	4,981,471 A	1/1991	Quinn et al.
4,627,844 A	12/1986	Schmitt	4,994,047 A	2/1991	Walker et al.
4,633,863 A	1/1987	Filips et al.	5,004,454 A	4/1991	Beyar et al.
4,634,433 A	1/1987	Osborne	5,007,897 A	4/1991	Kalb et al.
4,637,907 A	1/1987	Hegel	5,013,306 A	5/1991	Solomon et al.
4,638,790 A	1/1987	Conway et al.	5,013,717 A	5/1991	Solomon et al.
4,640,668 A	2/1987	Yang	5,019,096 A	5/1991	Fox, Jr. et al.
4,640,688 A	2/1987	Hauser	5,019,378 A	5/1991	Allen
4,652,259 A	3/1987	O'Neil	5,019,601 A	5/1991	Allen
4,664,657 A	5/1987	Williamitis et al.	5,059,190 A	10/1991	Novak
4,673,401 A	6/1987	Jensen et al.	5,071,406 A	12/1991	Jang
4,677,143 A	6/1987	Laurin et al.	5,078,707 A	1/1992	Peter Klug
4,685,913 A	8/1987	Austin	5,082,006 A	1/1992	Jonasson
4,686,124 A	8/1987	Onohara et al.	5,084,037 A	1/1992	Barnett
4,687,470 A	8/1987	Okada	5,087,252 A	2/1992	Denard
4,692,152 A	9/1987	Emde	5,088,980 A	2/1992	Leighton
4,699,616 A	10/1987	Nowak et al.	5,089,205 A	2/1992	Huang et al.
4,710,169 A	12/1987	Christopher	5,090,424 A	2/1992	Simon et al.
4,710,181 A	12/1987	Fuqua	5,098,379 A	3/1992	Conway et al.
4,731,064 A	3/1988	Heyden	5,102,401 A	4/1992	Lambert et al.
4,737,219 A	4/1988	Taller et al.	5,102,405 A	4/1992	Conway et al.
4,739,768 A	4/1988	Engelson	5,109,378 A	4/1992	Proctor et al.
4,747,845 A	5/1988	Korol	5,109,601 A	5/1992	McBride
4,754,877 A	7/1988	Johansson et al.	5,112,306 A	5/1992	Burton et al.
4,759,753 A	7/1988	Schneider et al.	5,114,398 A	5/1992	Trick et al.
4,768,503 A	9/1988	Highgate et al.	5,128,088 A	7/1992	Shimomura
4,769,013 A	9/1988	Lorenz et al.	5,131,906 A	7/1992	Chen
4,769,099 A	9/1988	Therriault et al.	5,137,671 A	8/1992	Conway et al.
4,772,473 A	9/1988	Ratel et al.	5,140,999 A	8/1992	Ardito
4,773,901 A	9/1988	Norton	5,147,341 A	9/1992	Starke et al.
4,775,371 A	10/1988	Mueller, Jr.	5,165,952 A	11/1992	Solomon et al.
4,790,834 A	12/1988	Austin	5,176,666 A	1/1993	Conway et al.
4,790,835 A *	12/1988	Elias ..... 604/349	5,197,957 A	3/1993	Wendler
D299,865 S	2/1989	Kamstrup-Larsen et al.	5,201,724 A	4/1993	Hukins et al.
4,810,247 A	3/1989	Glassman	5,209,726 A	5/1993	Goosen
4,811,847 A	3/1989	Reif et al.	5,211,640 A	5/1993	Wendler
4,813,935 A	3/1989	Haber et al.	5,226,530 A	7/1993	Golden
4,820,270 A	4/1989	Hardcastle et al.	5,234,411 A	8/1993	Vaillancourt
4,820,289 A	4/1989	Coury et al.	5,236,422 A	8/1993	Eplett, Jr.
4,820,291 A	4/1989	Terauchi et al.	5,242,391 A	9/1993	Place et al.
4,820,292 A	4/1989	Korol et al.	5,242,428 A	9/1993	Palestrant
4,834,721 A	5/1989	Onohara et al.	5,261,896 A	11/1993	Conway et al.
4,838,876 A	6/1989	Wong et al.	5,263,947 A	11/1993	Kay
4,846,784 A	7/1989	Haber	5,269,755 A	12/1993	Bodicky
4,846,909 A	7/1989	Klug et al.	5,269,770 A	12/1993	Conway et al.
4,850,969 A	7/1989	Jackson	5,270,358 A	12/1993	Asmus
4,861,337 A	8/1989	George	5,279,600 A *	1/1994	Hogan ..... 604/317
4,863,424 A	9/1989	Blake, III et al.	5,290,306 A	3/1994	Trotta et al.
4,863,444 A	9/1989	Blomer	5,300,052 A *	4/1994	Kubo ..... 604/349
4,863,449 A	9/1989	Therriault et al.	5,306,226 A	4/1994	Salama
4,867,748 A	9/1989	Samuelsen	5,334,175 A	8/1994	Conway et al.
4,874,373 A	10/1989	Luther	5,335,775 A	8/1994	Scanlon et al.
4,876,109 A	10/1989	Mayer et al.	5,336,211 A	8/1994	Metz
4,885,049 A	12/1989	Johannesson	5,346,483 A	9/1994	Thaxton, Sr.
4,894,059 A	1/1990	Larsen et al.	5,348,536 A	9/1994	Young et al.
4,902,503 A	2/1990	Umemura et al.	5,352,182 A	10/1994	Kalb et al.
4,904,260 A	2/1990	Ray et al.	5,360,402 A	11/1994	Conway et al.
4,917,113 A	4/1990	Conway et al.	5,366,449 A	11/1994	Gilberg
4,917,686 A	4/1990	Bayston et al.	5,368,575 A	11/1994	Chang
4,919,966 A	4/1990	Shlenker	5,370,899 A	12/1994	Conway et al.
RE33,206 E	5/1990	Conway et al.	5,376,085 A	12/1994	Conway et al.
4,923,450 A	5/1990	Maeda et al.	5,380,312 A	1/1995	Goulter
4,925,668 A	5/1990	Khan et al.	5,395,333 A	3/1995	Brill
4,930,522 A	6/1990	Busnel et al.	5,402,886 A	4/1995	McGlinch
4,931,056 A	6/1990	Ghajar et al.	5,409,495 A	4/1995	Osborn
			5,415,635 A	5/1995	Bagaoisan et al.
			5,417,226 A	5/1995	Juma
			5,417,666 A	5/1995	Coulter
			5,423,784 A	6/1995	Metz

(56)

References Cited

U.S. PATENT DOCUMENTS

5,433,705 A	7/1995	Giebel et al.	6,063,063 A	5/2000	Harboe et al.
5,433,713 A	7/1995	Trotta	6,065,597 A	5/2000	Pettersson et al.
5,447,231 A	9/1995	Kastenhofer	6,090,075 A	7/2000	House
5,451,424 A	9/1995	Solomon et al.	6,098,625 A *	8/2000	Winkler ..... 128/842
5,454,798 A	10/1995	Kubalak et al.	6,102,929 A	8/2000	Conway et al.
5,464,650 A	11/1995	Berg et al.	6,113,582 A *	9/2000	Dwork ..... 604/349
5,479,945 A	1/1996	Simon	6,119,697 A	9/2000	Engel et al.
5,482,740 A	1/1996	Conway et al.	6,131,575 A	10/2000	Lenker et al.
5,483,976 A	1/1996	McLaughlin et al.	6,132,399 A	10/2000	Shultz
5,501,669 A	3/1996	Conway et al.	6,186,990 B1	2/2001	Chen et al.
5,509,427 A	4/1996	Simon et al.	6,206,885 B1	3/2001	Ghahremani et al.
5,513,659 A	5/1996	Buuck et al.	6,231,501 B1	5/2001	Ditter
5,513,660 A	5/1996	Simon et al.	6,254,570 B1	7/2001	Rutner et al.
5,531,715 A	7/1996	Engelson et al.	6,261,255 B1	7/2001	Mullis et al.
5,531,717 A	7/1996	Roberto et al.	6,261,271 B1	7/2001	Solomon et al.
5,538,584 A	7/1996	Metz	6,280,425 B1	8/2001	Del Guercio
5,549,924 A	8/1996	Shlenker et al.	6,296,627 B1 *	10/2001	Edwards ..... 604/347
5,554,141 A	9/1996	Wendler	6,299,598 B1	10/2001	Bander
5,562,599 A	10/1996	Beyschlag	6,315,711 B1	11/2001	Conway et al.
5,567,495 A	10/1996	Modak et al.	6,326,421 B1	12/2001	Lipman
5,569,219 A	10/1996	Hakki et al.	6,355,004 B1	3/2002	Pedersen et al.
5,582,599 A	12/1996	Daneshvar	6,379,334 B1	4/2002	Frassica
5,593,718 A	1/1997	Conway et al.	6,383,434 B2	5/2002	Conway et al.
5,599,321 A	2/1997	Conway et al.	6,387,080 B1	5/2002	R.o slashed.dsten
5,614,143 A	3/1997	Hager	6,391,010 B1	5/2002	Wilcox
5,622,711 A	4/1997	Chen	6,402,726 B1	6/2002	Genese
5,624,395 A	4/1997	Mikhail et al.	6,409,717 B1	6/2002	Israelsson et al.
5,630,429 A	5/1997	Dann	6,437,038 B1	8/2002	Chen
5,633,010 A	5/1997	Chen	6,440,060 B1	8/2002	Latour, Jr.
5,643,235 A *	7/1997	Figuerido ..... 604/352	6,468,245 B2	10/2002	Alexandersen et al.
5,670,111 A	9/1997	Conway et al.	6,479,000 B2	11/2002	Conway et al.
5,670,557 A	9/1997	Dietz et al.	6,479,726 B1 *	11/2002	Cole ..... 604/358
5,671,755 A	9/1997	Simon et al.	6,509,319 B1	1/2003	Raad et al.
5,674,561 A	10/1997	Dietz et al.	6,551,293 B1	4/2003	Mitchell
5,679,399 A	10/1997	Shlenker et al.	6,558,369 B2	5/2003	Rosenblum
5,695,485 A *	12/1997	Duperret et al. .... 604/349	6,558,792 B1	5/2003	Vaabengaard et al.
5,702,381 A	12/1997	Cottenden	6,578,709 B1	6/2003	Kavanagh et al.
5,707,357 A	1/1998	Mikhail et al.	6,579,539 B2	6/2003	Lawson et al.
5,709,672 A	1/1998	Illner	6,582,401 B1	6/2003	Windheuser et al.
5,711,841 A	1/1998	Jaker	6,596,401 B1	7/2003	Terry et al.
5,724,994 A	3/1998	Simon et al.	6,602,244 B2	8/2003	Kavanagh et al.
5,730,733 A	3/1998	Mortier et al.	6,613,014 B1	9/2003	Chi
5,736,152 A	4/1998	Dunn	6,626,888 B1	9/2003	Conway et al.
5,752,525 A	5/1998	Simon et al.	6,632,204 B2	10/2003	Guldfeldt et al.
5,756,144 A	5/1998	Wolff et al.	6,634,498 B2	10/2003	Kayerod et al.
5,762,996 A	6/1998	Lucas et al.	6,638,269 B2	10/2003	Wilcox
5,779,632 A	7/1998	Dietz et al.	6,659,937 B2	12/2003	Polsky et al.
5,779,670 A	7/1998	Bidwell et al.	6,682,555 B2	1/2004	Cioanta et al.
5,795,332 A	8/1998	Lucas et al.	6,693,189 B2	2/2004	Holt et al.
5,795,334 A	8/1998	Cochrane, III	6,695,831 B1	2/2004	Tsukada et al.
5,795,524 A	8/1998	Basso, Jr. et al.	6,716,895 B1	4/2004	Terry
5,806,527 A	9/1998	Borodulin et al.	6,719,709 B2	4/2004	Whalen et al.
5,810,789 A	9/1998	Powers et al.	6,723,350 B2	4/2004	Burrell et al.
5,820,607 A	10/1998	Tcholakian et al.	6,733,474 B2	5/2004	Kusleika
5,827,247 A	10/1998	Kay	6,736,805 B2	5/2004	Israelsson et al.
5,827,249 A	10/1998	Jensen	6,740,273 B2	5/2004	Lee
5,830,932 A	11/1998	Kay	6,767,551 B2	7/2004	McGhee et al.
5,853,518 A	12/1998	Utas et al.	D496,266 S	9/2004	Nestenborg et al.
5,853,750 A	12/1998	Dietz et al.	6,787,156 B1	9/2004	Bar-Shalom
5,877,243 A	3/1999	Sarangapani	6,797,743 B2	9/2004	McDonald et al.
5,895,374 A	4/1999	Rodsten et al.	6,803,420 B2	10/2004	Cleary et al.
5,897,535 A	4/1999	Feliziani et al.	6,848,574 B1	2/2005	Israelsson et al.
5,902,631 A	5/1999	Wang et al.	6,849,070 B1	2/2005	Hansen et al.
5,906,575 A	5/1999	Conway et al.	6,852,105 B2	2/2005	Bolmsjo et al.
5,931,303 A	8/1999	Salvadori	D503,335 S	3/2005	Risberg et al.
5,931,304 A	8/1999	Hammond	6,869,416 B2	3/2005	Windheuser et al.
5,971,954 A	10/1999	Conway et al.	6,872,195 B2	3/2005	Modak et al.
5,980,483 A	11/1999	Dimitri	6,887,230 B2	5/2005	Kubalak et al.
5,980,507 A	11/1999	Fassuliotis et al.	6,939,339 B1	9/2005	Axexandersen et al.
6,004,305 A	12/1999	Hursman et al.	6,939,554 B2	9/2005	McDonald et al.
6,007,524 A	12/1999	Schneider	6,949,090 B1 *	9/2005	Leers et al. .... 604/386
6,007,526 A	12/1999	Passalaqua et al.	6,951,902 B2	10/2005	McDonald et al.
6,050,934 A	4/2000	Mikhail et al.	7,001,370 B2	2/2006	Kubalak et al.
6,053,905 A	4/2000	Daignault, Jr. et al.	7,033,367 B2	4/2006	Ghahremani et al.
6,059,107 A	5/2000	Nosted et al.	7,066,912 B2	6/2006	Nestenborg et al.
			7,087,048 B2	8/2006	Israelsson et al.
			7,094,220 B2	8/2006	Tanghoj et al.
			7,160,277 B2	1/2007	Elson et al.
			7,166,092 B2	1/2007	Elson et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

7,204,940 B2	4/2007	McDonald et al.	2003/0018302 A1	1/2003	Kavanagh et al.
7,211,275 B2	5/2007	Ying et al.	2003/0018321 A1	1/2003	Rosenblum
7,294,117 B2	11/2007	Provost-tine et al.	2003/0018322 A1	1/2003	Tanghoj et al.
7,311,698 B2	12/2007	Tanghoj et al.	2003/0055403 A1	3/2003	Nestenborg et al.
7,329,412 B2	2/2008	Modak et al.	2003/0060807 A1	3/2003	Tanghoj et al.
7,331,948 B2	2/2008	Skarda	2003/0083644 A1	5/2003	Avaltroni
7,334,679 B2	2/2008	Givens, Jr.	2003/0130646 A1	7/2003	Kubalak et al.
7,374,040 B2	5/2008	Lee et al.	2003/0168365 A1	9/2003	Kaern
7,380,658 B2	6/2008	Murray et al.	2004/0030301 A1	2/2004	Hunter
7,381,768 B2	6/2008	Wiercinski et al.	2004/0055925 A1	3/2004	Franks-Farah et al.
7,402,559 B2	7/2008	Catania et al.	2004/0074794 A1	4/2004	Conway et al.
7,445,812 B2	11/2008	Schmidt et al.	2004/0097892 A1	5/2004	Evans et al.
7,458,964 B2	12/2008	Mosler et al.	2004/0133156 A1	7/2004	Diaz et al.
7,476,223 B2	1/2009	McBride	2004/0153049 A1	8/2004	Hewitt et al.
7,507,229 B2	3/2009	Hewitt et al.	2004/0153051 A1	8/2004	Israelsson et al.
7,517,343 B2	4/2009	Tanghoj et al.	2004/0158231 A1	8/2004	Tanghoj et al.
7,571,804 B2	8/2009	Kjellmann Bruun et al.	2004/0163980 A1	8/2004	Tanghoj et al.
7,601,158 B2	10/2009	House	2004/0193143 A1	9/2004	Sauer
7,615,045 B2	11/2009	Israelsson et al.	2004/0234572 A1	11/2004	Martinod et al.
7,628,784 B2	12/2009	Diaz et al.	2004/0236293 A1	11/2004	Tanghoj et al.
7,632,256 B2	12/2009	Mosler et al.	2004/0249343 A1	12/2004	Cioanta
D609,819 S	2/2010	Tomes et al.	2004/0254562 A1	12/2004	Tanghoj et al.
7,662,146 B2	2/2010	House	2004/0256264 A1	12/2004	Israelsson et al.
7,670,331 B2	3/2010	Tanghoej	2005/0015076 A1	1/2005	Giebmeier et al.
7,682,353 B2	3/2010	Tanghoj et al.	2005/0031872 A1	2/2005	Schmidt et al.
7,691,476 B2	4/2010	Finley	2005/0043715 A1	2/2005	Nestenborg et al.
7,717,902 B2	5/2010	Sauer	2005/0049577 A1	3/2005	Snell et al.
7,749,529 B2	7/2010	Ash et al.	2005/0070882 A1	3/2005	McBride
7,767,291 B2	8/2010	Taylor	2005/0080399 A1	4/2005	Bolmsjo et al.
7,770,726 B2	8/2010	Murray et al.	2005/0096688 A1	5/2005	Slazas et al.
7,770,728 B2	8/2010	K.ae butted.m	2005/0101924 A1*	5/2005	Elson et al. .... 604/349
7,780,642 B2	8/2010	Rasmussen et al.	2005/0109648 A1	5/2005	Kerzman et al.
7,789,873 B2	9/2010	Kubalak et al.	2005/0137582 A1	6/2005	Kull-Osterlin et al.
7,823,722 B2	11/2010	Bezou et al.	2005/0148950 A1	7/2005	Windheuser et al.
7,846,133 B2	12/2010	Windheuser et al.	2005/0177104 A1	8/2005	Conway
7,867,220 B2	1/2011	Tanghoj	2005/0199521 A1	9/2005	Givens
7,886,907 B2	2/2011	Murray et al.	2005/0214443 A1	9/2005	Madsen
7,918,831 B2	4/2011	House	2005/0282977 A1	12/2005	Stempel et al.
7,938,838 B2	5/2011	House	2005/0283136 A1	12/2005	Skarda
7,947,021 B2	5/2011	Bourne et al.	2006/0004332 A1*	1/2006	Marx ..... 604/349
7,985,217 B2	7/2011	Mosler et al.	2006/0025753 A1	2/2006	Kubalak et al.
8,011,505 B2	9/2011	Murray et al.	2006/0041246 A1	2/2006	Provost-tine et al.
8,051,981 B2	11/2011	Murray et al.	2006/0058777 A1	3/2006	Nielsen
8,052,673 B2	11/2011	Nestenborg	2006/0163097 A1	7/2006	Murray et al.
8,058,341 B2	11/2011	Tosaki et al.	2006/0196783 A1	9/2006	Bruun et al.
8,066,693 B2	11/2011	Tanghoj et al.	2006/0229576 A1	10/2006	Conway et al.
8,127,922 B2	3/2012	Nordholm et al.	2006/0240069 A1	10/2006	Utas et al.
8,163,327 B2	4/2012	Finley	2007/0016168 A1	1/2007	Conway
8,177,774 B2	5/2012	House	2007/0088330 A1	4/2007	House
8,181,778 B1	5/2012	Van Groningen et al.	2007/0161971 A1	7/2007	House
8,192,413 B2	6/2012	Bjerregaard	2008/0015527 A1	1/2008	House
8,205,745 B2	6/2012	Murray et al.	2008/0091145 A1	4/2008	House
8,207,393 B2	6/2012	Bach	2008/0103464 A1	5/2008	Mosler et al.
8,230,993 B2	7/2012	Tanghoej	2008/0172040 A1	7/2008	Smith
8,267,919 B2	9/2012	Utas et al.	2008/0172042 A1	7/2008	House
8,282,624 B2	10/2012	Tanghoej et al.	2008/0179208 A1	7/2008	Murray et al.
8,287,519 B2	10/2012	Smith	2008/0183262 A1	7/2008	Dowling
8,298,202 B2	10/2012	McCray	2008/0215021 A1	9/2008	Cisko Jr. et al.
8,303,556 B2	11/2012	White	2008/0243081 A1	10/2008	Nance et al.
8,328,792 B2	12/2012	Nishtala et al.	2008/0279907 A1	11/2008	Ash et al.
8,356,457 B2	1/2013	Murray et al.	2009/0000970 A1	1/2009	Bordeau et al.
8,409,171 B2	4/2013	Hannon et al.	2009/0005725 A1	1/2009	Shorey
8,454,569 B2	6/2013	Kull-Osterlin et al.	2009/0043287 A1	2/2009	Mosler et al.
8,459,455 B2	6/2013	Frojd	2009/0048570 A1	2/2009	Jensen
8,475,434 B2	7/2013	Frojd	2009/0101531 A1	4/2009	Nordholm et al.
2001/0001443 A1	5/2001	Kayerod et al.	2009/0131917 A1	5/2009	Kavanagh et al.
2001/0031933 A1*	10/2001	Cannon ..... 600/580	2009/0163884 A1	6/2009	Kull-Osterlin et al.
2001/0054562 A1	12/2001	Pettersson et al.	2009/0200187 A1	8/2009	Nestenborg et al.
2002/0032406 A1	3/2002	Kusleika	2009/0221992 A1	9/2009	Hannon et al.
2002/0103467 A1	8/2002	Kubalak	2009/0234294 A1	9/2009	Harvey et al.
2002/0147265 A1	10/2002	Ding et al.	2009/0240214 A1	9/2009	Conway et al.
2002/0169438 A1	11/2002	Sauer	2010/0010086 A1	1/2010	Ash et al.
2002/0182265 A1	12/2002	Burrell et al.	2010/0025273 A1	2/2010	Matsuda et al.
2003/0004496 A1	1/2003	Tanghoj	2010/0030197 A1	2/2010	House
2003/0018293 A1	1/2003	Tanghoj et al.	2010/0036363 A1	2/2010	Watanabe et al.
			2010/0133172 A1	6/2010	Song et al.
			2010/0155268 A1	6/2010	Murray et al.
			2010/0200002 A1	8/2010	Orban, III et al.
			2010/0256576 A1	10/2010	Aggarwal et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

2010/0322996 A1 12/2010 Wibaux et al.  
 2011/0056852 A1 3/2011 Frojd  
 2011/0114520 A1 5/2011 Matthison-Hansen  
 2011/0118670 A1 5/2011 Kay et al.  
 2011/0137296 A1 6/2011 Tanghoj  
 2011/0152843 A1 6/2011 Wedlin et al.  
 2011/0178507 A1 7/2011 Bracken et al.  
 2011/0184386 A1 7/2011 House  
 2011/0213025 A1 9/2011 Finch, Jr.  
 2011/0284409 A1 11/2011 Murray et al.  
 2012/0029451 A1 2/2012 Conway  
 2012/0179144 A1 7/2012 Carleo  
 2012/0203182 A1 8/2012 Kay et al.  
 2012/0228165 A1 9/2012 Murray et al.  
 2012/0271101 A1 10/2012 Tan  
 2012/0316515 A1 12/2012 Terry  
 2013/0006226 A1 1/2013 Hong et al.  
 2013/0037306 A1 2/2013 Kim  
 2013/0131647 A1 5/2013 Nielsen  
 2013/0138083 A1 5/2013 Tennican  
 2013/0138088 A1 5/2013 Nielsen  
 2013/0153446 A1 6/2013 Utas et al.  
 2014/0142554 A1 5/2014 Conway et al.  
 2014/0142555 A1 5/2014 Conway et al.

## FOREIGN PATENT DOCUMENTS

DE 1913976 U 4/1965  
 DE 4135502 2/1993  
 DE 19826746 C1 11/1999  
 EP 0 055 023 A2 6/1982  
 EP 0182409 A1 5/1986  
 EP 0 184 629 A2 6/1986  
 EP 0187846 A1 7/1986  
 EP 0193406 A2 9/1986  
 EP 0217771 4/1987  
 EP 0218203 A1 4/1987  
 EP 0236458 A1 9/1987  
 EP 0252918 A1 1/1988  
 EP 0298634 A1 1/1989  
 EP 0 303 487 A3 2/1989  
 EP 0335564 A1 10/1989  
 EP 0352043 A1 1/1990  
 EP 0390720 A1 10/1990  
 EP 0407218 A1 1/1991  
 EP 0471553 A1 2/1992  
 EP 0479935 A1 4/1992  
 EP 0528965 A1 3/1993  
 EP 0553960 A1 8/1993  
 EP 0590104 A1 4/1994  
 EP 0598191 A1 5/1994  
 EP 0663196 A1 7/1995  
 EP 0677299 10/1995  
 EP 0680895 A1 11/1995  
 EP 0685179 A1 12/1995  
 EP 0699086 A1 3/1996  
 EP 0767639 A1 4/1997  
 EP 0768069 A1 4/1997  
 EP 0815037 A1 1/1998  
 EP 0909249 A1 4/1999  
 EP 0923398 6/1999  
 EP 0935478 A1 8/1999  
 EP 0959930 12/1999  
 EP 0977610 A2 2/2000  
 EP 1023882 8/2000  
 EP 1090656 4/2001  
 EP 1115450 A1 7/2001  
 EP 1131022 A1 9/2001  
 EP 1145729 10/2001  
 EP 1245205 10/2002  
 EP 1308146 5/2003  
 EP 1347723 A1 10/2003  
 EP 1406690 A2 4/2004  
 EP 1427467 A2 6/2004

EP 1 047 360 B1 10/2004  
 EP 1485158 A2 12/2004  
 EP 1498151 1/2005  
 EP 1578308 A1 9/2005  
 EP 1606196 A2 12/2005  
 EP 1615690 A1 1/2006  
 EP 1629799 A1 3/2006  
 EP 1641510 A1 4/2006  
 EP 1642610 4/2006  
 EP 1642611 4/2006  
 EP 1647298 A2 4/2006  
 EP 1786501 A2 5/2007  
 EP 1788990 A1 5/2007  
 EP 1793938 A1 6/2007  
 EP 1799163 A1 6/2007  
 EP 1904003 A2 4/2008  
 EP 1948279 A1 7/2008  
 EP 1955683 A1 8/2008  
 EP 2216064 A1 8/2010  
 EP 2226041 A2 9/2010  
 EP 2226042 A2 9/2010  
 EP 2258435 A1 12/2010  
 EP 2275058 A1 1/2011  
 EP 2292293 A1 3/2011  
 EP 2292294 A1 3/2011  
 EP 2423125 A1 2/2012  
 EP 2423126 A1 2/2012  
 EP 2423127 A1 2/2012  
 EP 2450076 A1 5/2012  
 EP 2468347 A1 6/2012  
 FR 1558162 A 2/1969  
 FR 2794638 A1 12/2000  
 FR 2855399 A1 12/2004  
 GB 322426 A 12/1929  
 GB 1131865 A 10/1968  
 GB 2150938 A 7/1985  
 GB 2187670 A 9/1987  
 JP 0218157 12/1984  
 JP 0228856 12/1984  
 WO 84/01102 3/1984  
 WO 8600816 A1 2/1986  
 WO 8606284 11/1986  
 WO 8701582 A1 3/1987  
 WO 89/09626 10/1989  
 WO 90/04431 5/1990  
 WO 9110467 A1 7/1991  
 WO 91/10466 7/1991  
 WO 9117728 A1 11/1991  
 WO 92/08426 5/1992  
 WO 9210220 A1 6/1992  
 WO 9211826 A1 7/1992  
 WO 9219192 A1 11/1992  
 WO 9300054 A1 1/1993  
 WO 9311821 A1 6/1993  
 WO 93/14806 8/1993  
 WO 9406377 A1 3/1994  
 WO 9416747 A1 8/1994  
 WO 9426215 A1 11/1994  
 WO 9508968 A1 4/1995  
 WO 9509667 A1 4/1995  
 WO 9517862 A1 7/1995  
 WO 9534253 A1 12/1995  
 WO 9600541 A1 1/1996  
 WO 9604119 A1 2/1996  
 WO 9619254 A1 6/1996  
 WO 9626688 A1 9/1996  
 WO 9630277 A1 10/1996  
 WO 9634587 A1 11/1996  
 WO 9638192 A1 12/1996  
 WO 9639096 A1 12/1996  
 WO 9725947 A1 7/1997  
 WO 9726937 7/1997  
 WO 9741811 11/1997  
 WO 9806642 A1 2/1998  
 WO 9907313 A1 2/1999  
 WO 9930761 A1 6/1999  
 WO 99/36009 7/1999  
 WO 0025848 A2 5/2000  
 WO 0030575 A1 6/2000

(56)

## References Cited

## FOREIGN PATENT DOCUMENTS

WO	0047494	8/2000
WO	0143807	6/2001
WO	0152763	7/2001
WO	0193935	12/2001
WO	0236192	5/2002
WO	02053070 A1	7/2002
WO	02060361 A2	8/2002
WO	03002178	1/2003
WO	03008029 A2	1/2003
WO	03022333 A1	3/2003
WO	03064279 A1	8/2003
WO	03092779	11/2003
WO	2004004611 A1	1/2004
WO	2004004796 A1	1/2004
WO	2004030722	4/2004
WO	2004032992 A2	4/2004
WO	2004045696	6/2004
WO	2004050155	6/2004
WO	2004052440	6/2004
WO	2004056290 A1	7/2004
WO	2004056414	7/2004
WO	2004056909 A1	7/2004
WO	2004075944	9/2004
WO	2004089454	10/2004
WO	2005004964	1/2005
WO	2005014055 A2	2/2005
WO	2005061035	7/2005
WO	2005092418	10/2005
WO	2006005349 A2	1/2006
WO	2006009509 A1	1/2006
WO	2006009596 A1	1/2006
WO	2006017439 A2	2/2006
WO	2006021590 A1	3/2006
WO	2006027349 A1	3/2006
WO	2006097109 A2	9/2006
WO	2006110695 A2	10/2006
WO	2006112782 A1	10/2006
WO	2006130776 A2	12/2006
WO	2007001526 A2	1/2007
WO	2007038988 A1	4/2007
WO	2007083033 A2	7/2007
WO	2008089770 A1	7/2008
WO	2008104603 A1	9/2008
WO	2008138351 A1	11/2008
WO	2008138352 A1	11/2008
WO	2009000277 A1	12/2008
WO	2009043872 A1	4/2009
WO	2009068043 A2	6/2009
WO	2009080265 A1	7/2009
WO	2009108243 A1	9/2009
WO	2010006620 A1	1/2010
WO	2010054659 A1	5/2010
WO	2010054666 A1	5/2010
WO	2010129362 A1	11/2010
WO	2010130261 A1	11/2010
WO	2010149174 A1	12/2010
WO	2010149175 A1	12/2010
WO	2010151682 A2	12/2010
WO	2011011023 A1	1/2011
WO	2011014201 A1	2/2011
WO	2011019359 A1	2/2011
WO	2011026929 A1	3/2011
WO	2011026930 A1	3/2011
WO	2011063816 A1	6/2011
WO	2011073403 A1	6/2011
WO	2011076211 A1	6/2011
WO	2011079129 A1	6/2011
WO	2011109393 A1	9/2011
WO	2012016570 A2	2/2012
WO	2012016571 A2	2/2012
WO	2012018402 A1	2/2012
WO	2012079590 A1	6/2012
WO	2012134804 A1	10/2012
WO	2013010745 A1	1/2013

WO	2013029621 A1	3/2013
WO	2014081853 A1	5/2014
WO	2014081859 A1	5/2014

## OTHER PUBLICATIONS

“Liberty Pouch Instructions,” BioDerm, Inc., 2 pages (Publicly known prior to the filing date of the present application).

The Bard Hospital Division brochure by C. R. Bard, Inc., Murray Hill, N.J. 07974, 4 pages (copyright on a date unknown prior to Nov. 9, 1989).

“The Merck Index: Ninth Edition”, Merck and Co., Inc., p. 857 (1976).

Bayston, R., “The Antibacterial Effects of Impregnated Silastic and its Possible Applications in Surgery”, *J. Pediatric Surgery*, vol. 12, No. 1, pp. 55-61 (Feb. 1977).

Bayston, R., “Preliminary Studies on the Impregnation of Silastic Elastomers with Antimicrobial Substances”, *Devel. Medicine and Child Neurol.*, Suppl. 37, vol. 18, pp. 50-54 (1976).

Brocklehurst, J. et al., “The Management of Indwelling Catheters”, *Brit. J. Urology*, vol. 50, pp. 102-105 (1978).

Butler, H. et al., “Evaluation of Polymyxin Catheter Lubricant and Impregnated Catheters”, *J. Urology*, vol. 100, pp. 560-566 (Oct. 1968).

Lazarus, S. et al., “A Hydrophilic Polymer-Coated Antimicrobial Urethral Catheter”, *J. Biomed. Mater. Res.*, vol. 5, pp. 129-138 (1971).

Miura, K. et al., “The Nitrofurans, in Progress in Medicine Chemistry”; vol. 5 (G.P. Ellis & G.B. West, Eds.); New York, N. Y.; Plenum; pp. 320-381 (1967).

Mooro, H. et al., “Prevention of Catheter Fever by the Use of Furacin Urethral Inserts”, *J. Egypt Med. Assoc. (Egypt)*, vol. 49, No. 8, pp. 550-553 (1966).

Nielsen, K. et al., “The Urethral Plug: A New Treatment Modality for Genuine Urinary Stress Incontinence in Women” *The Journal of Urology*, vol. 144, No. 5, pp. 1199-1202 (Nov. 1990).

Nielsen, K. et al., “The Urethral Plug II: An Alternative Treatment in Women with Genuine Urinary Stress Incontinence”, *British Journal of Urology*, vol. 72, pp. 428-432 (1993).

Nosher, J. et al., “Antibiotic Bonded Nephrostomy Catheters for Percutaneous Nephrostomies”, *Cardiovasc. Interventional Radiol.*, vol. 13, pp. 102-106 (1990).

Rushton, D. et al., “Implant Infections and Antibiotic-Impregnated Silicone Rubber Coating”, *J. Neurol Neurosurg., Psych.*, vol. 52, pp. 223-229 (1989).

Sakamoto, I. et al., “Efficacy of an Antibiotic Coated Indwelling Catheter: A Preliminary Report”, *J. Biomed. Materials Res.*, vol. 19, pp. 1031-1041 (1985).

Shah, Z. et al., “Capsular Contracture Around Silicone Implants: The Role of Intraluminal Antibiotics”, *Plastic and Reconstr. Surg.*, vol. 69, No. 5, pp. 809-814 (May 1982).

Van Noort, R. et al., “Mechanical Properties of Antibacterial Silicone Rubber for Hydrocephalus Shunts”, *J. Biomed. Materials Res.*, vol. 13, pp. 623-630 (1979).

Amirkhalili, Saeid et al., “Nitric Oxide Complexes of Trimethylaluminium,” *Jornal of Organometallic Chemistry*, 149 (Jan. 20, 1978) 407-411.

Angus Chemie GmbH Technical Data Sheet for AMP-95 dated Mar. 6, 2006.

Ethomeen C/25 Information Sheet dated Jul. 28, 2005.

Johnson, James et al., “Activities of a Nitrofurazone-Containing Urinary Catheter and a Silver Hydrogel Catheter against Multidrug-Resistant Bacteria Characteristic of Catheter-Associated Urinary Tract Infection,” *Antimicrobial Agents and Chemotherapy*, col. 43, No. 12, Dec. 1999, pp. 2990-2995.

Lubrizol Technical Data Sheet, Neutralizing Carbopol® and Pemulen™ Polymers in Aqueous and Hydroalcoholic Systems, Sep. 16, 2009.

Newman, Diane et al., “Review of Intermittent Catheterization and Current Best Practices,” *Urol Nurs*. 2011:31(1).

PCT/US13/71046 filed Nov. 20, 2013 International Search Report and Written Opinion dated Feb. 21, 2014.

(56)

**References Cited**

OTHER PUBLICATIONS

PCT/US13/71060 filed Nov. 20, 2013 International Search Report and Written Opinion dated Jan. 30, 2014.

U.S. Appl. No. 13/047,175, filed Mar. 14, 2011, Final Office Action dated Mar. 17, 2014.

U.S. Appl. No. 13/682,406, filed Nov. 20, 2012, Non-Final Office Action dated Apr. 21, 2014.

U.S. Appl. No. 13/682,420, filed Nov. 20, 2012, Non-Final Office Action dated Apr. 2, 2014.

Vapro Product Brochure, 2009.

\* cited by examiner



FIG. 1

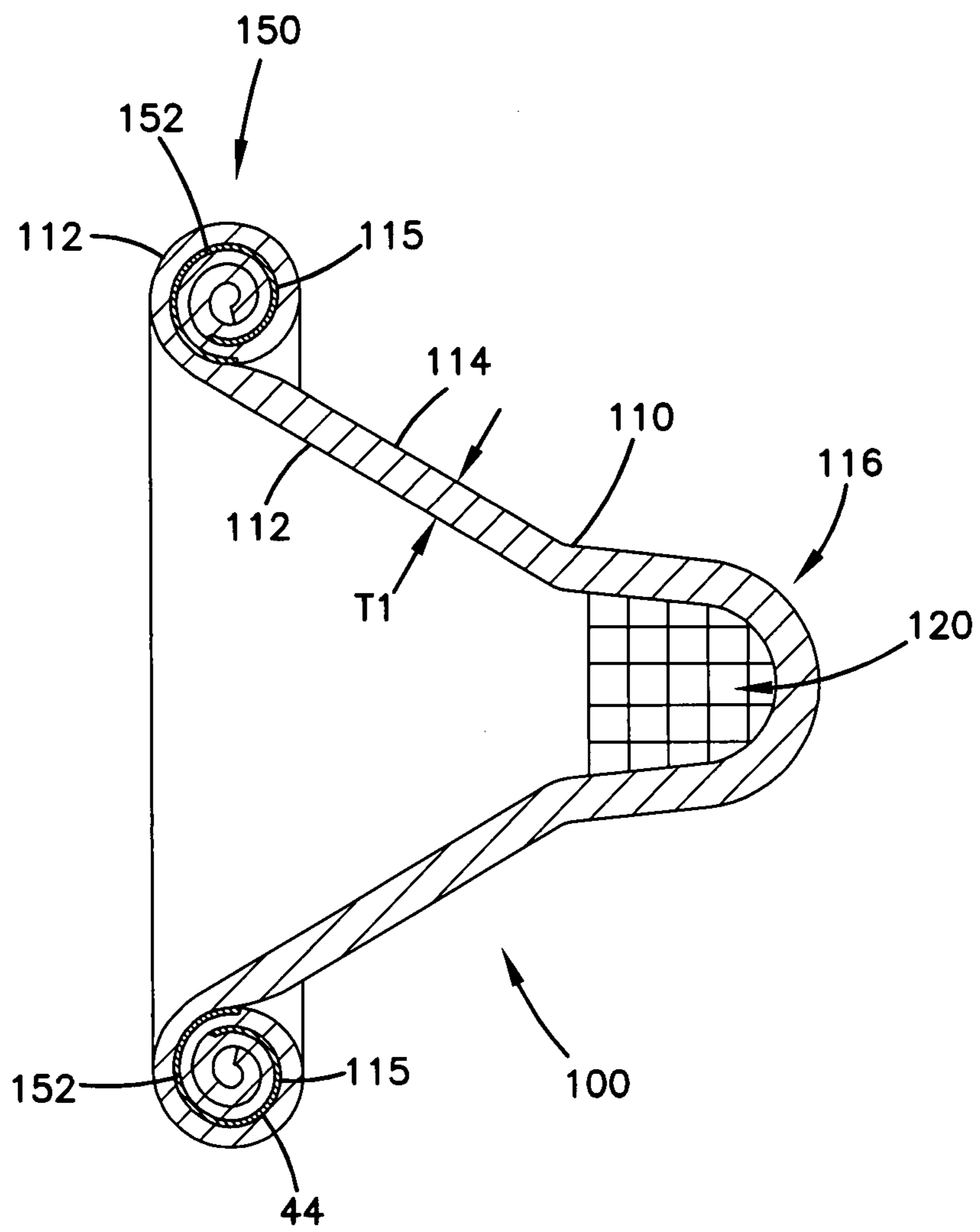


FIG. 2

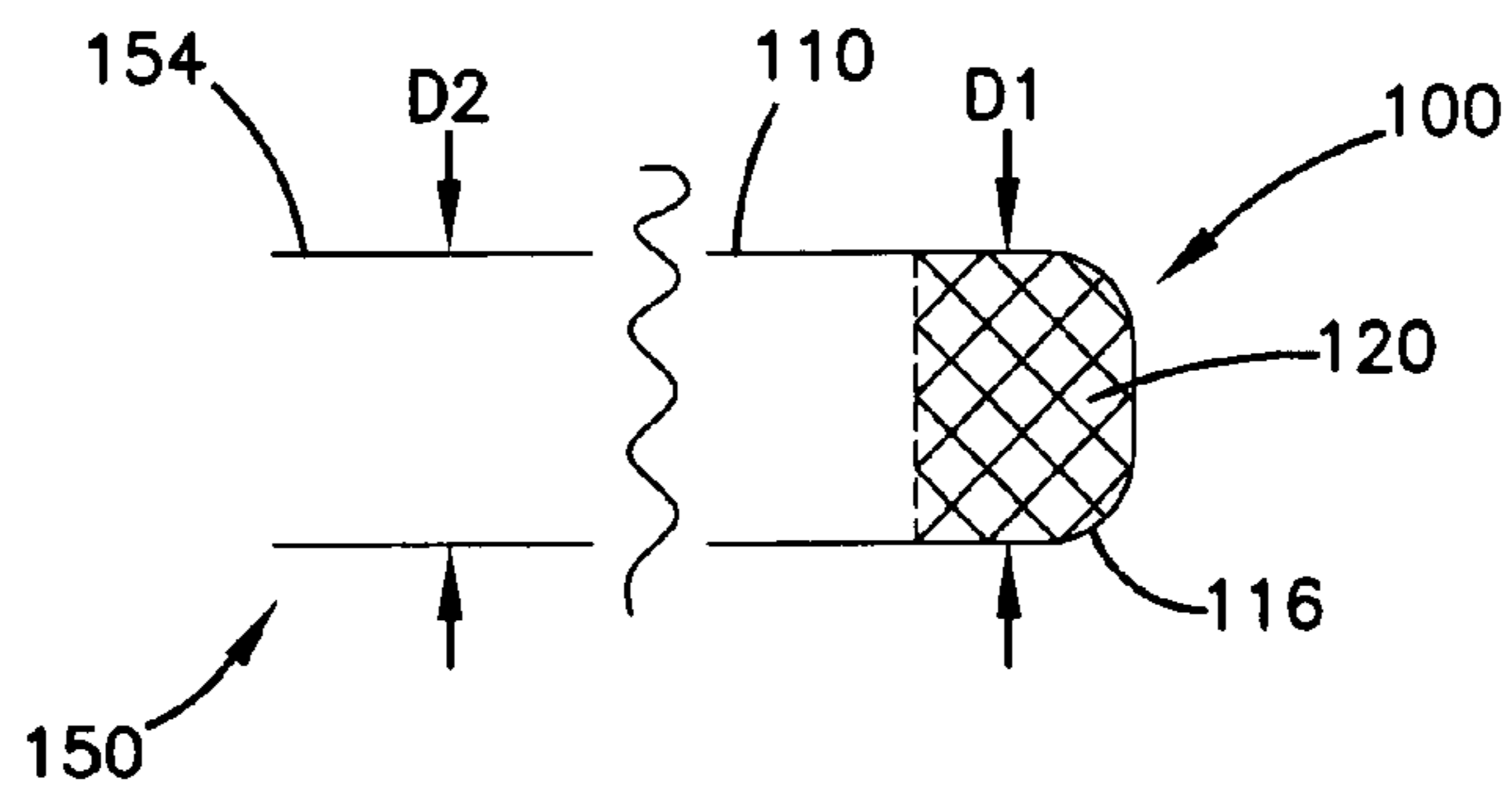


FIG. 3

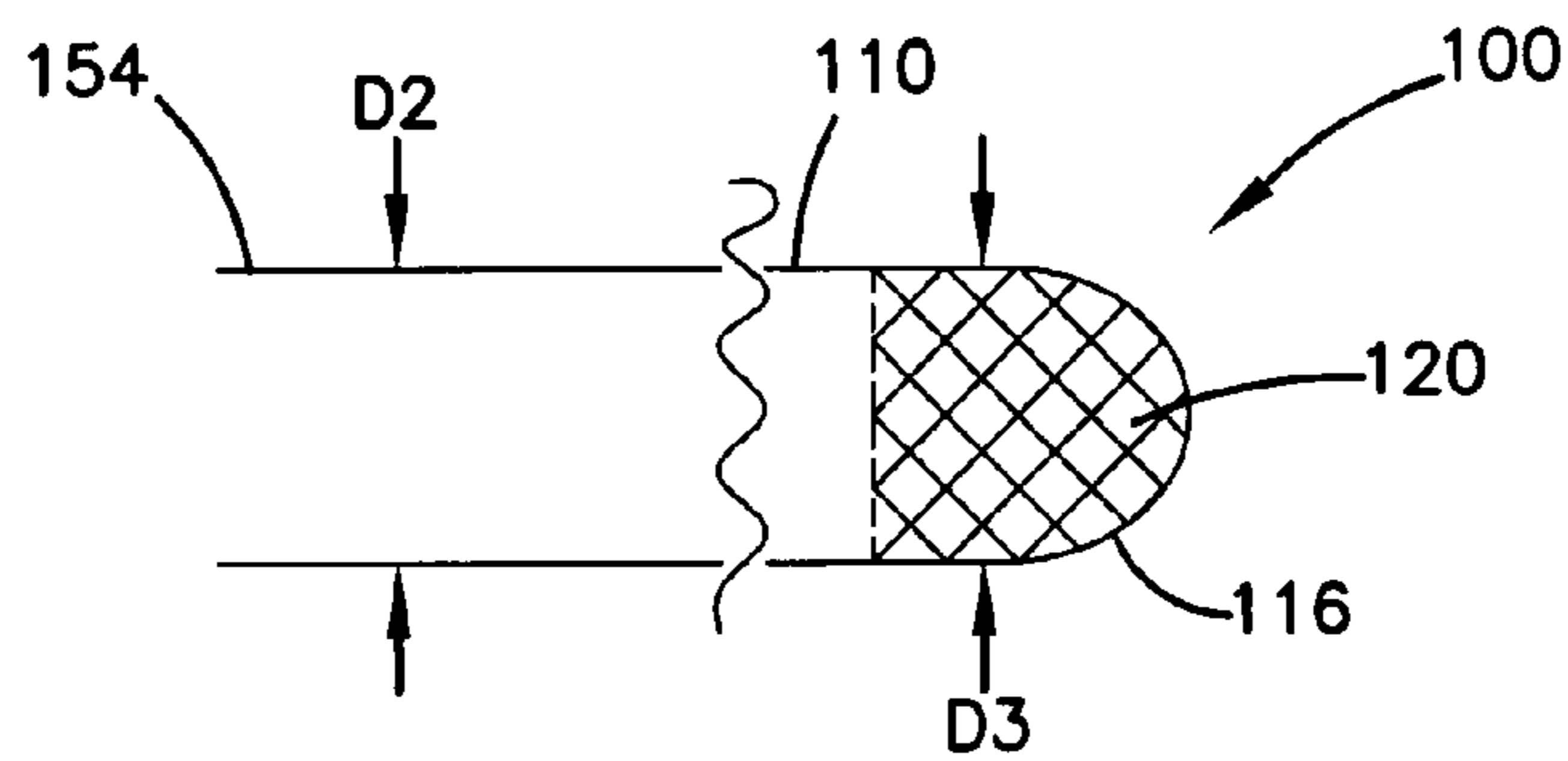


FIG. 4

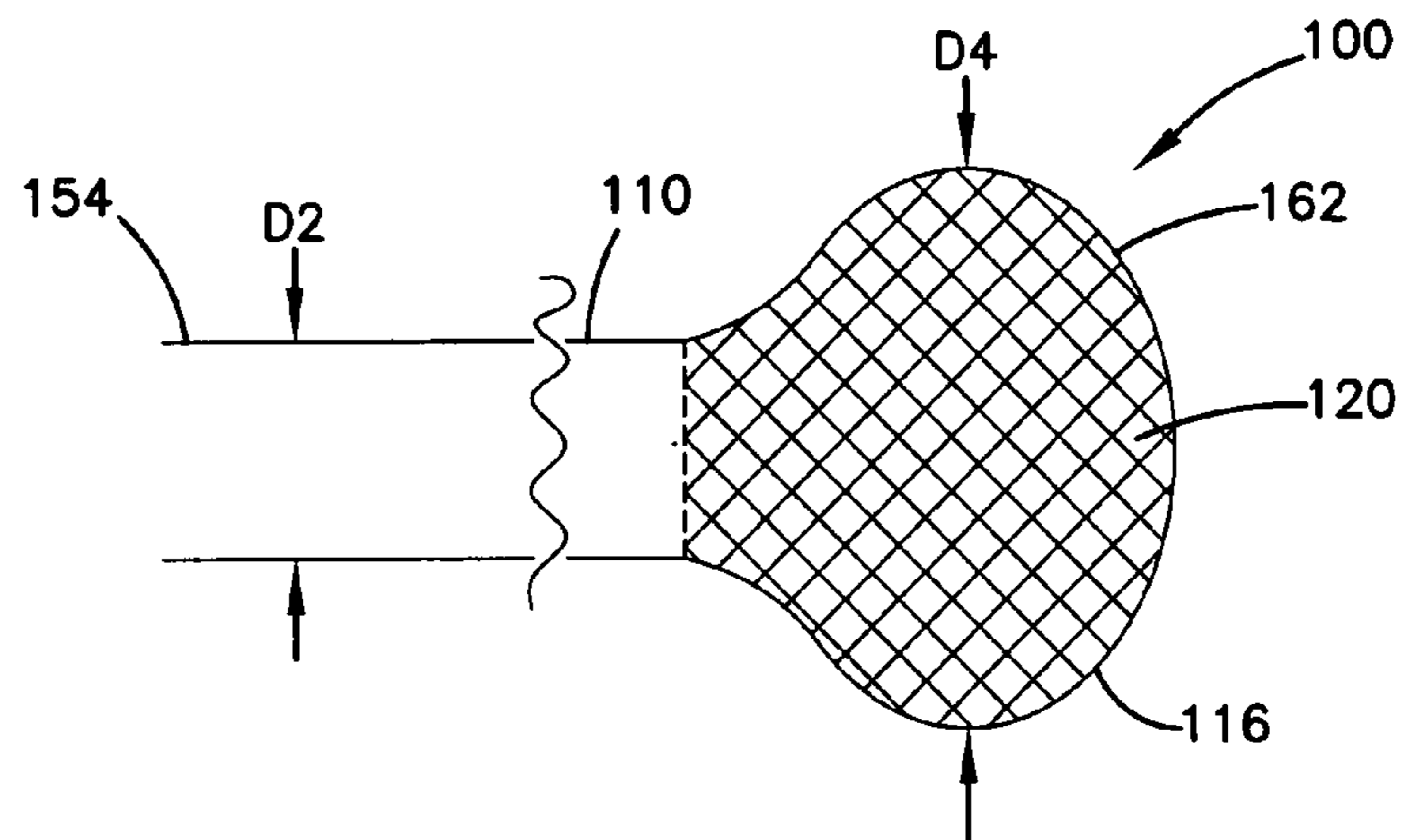


FIG. 5

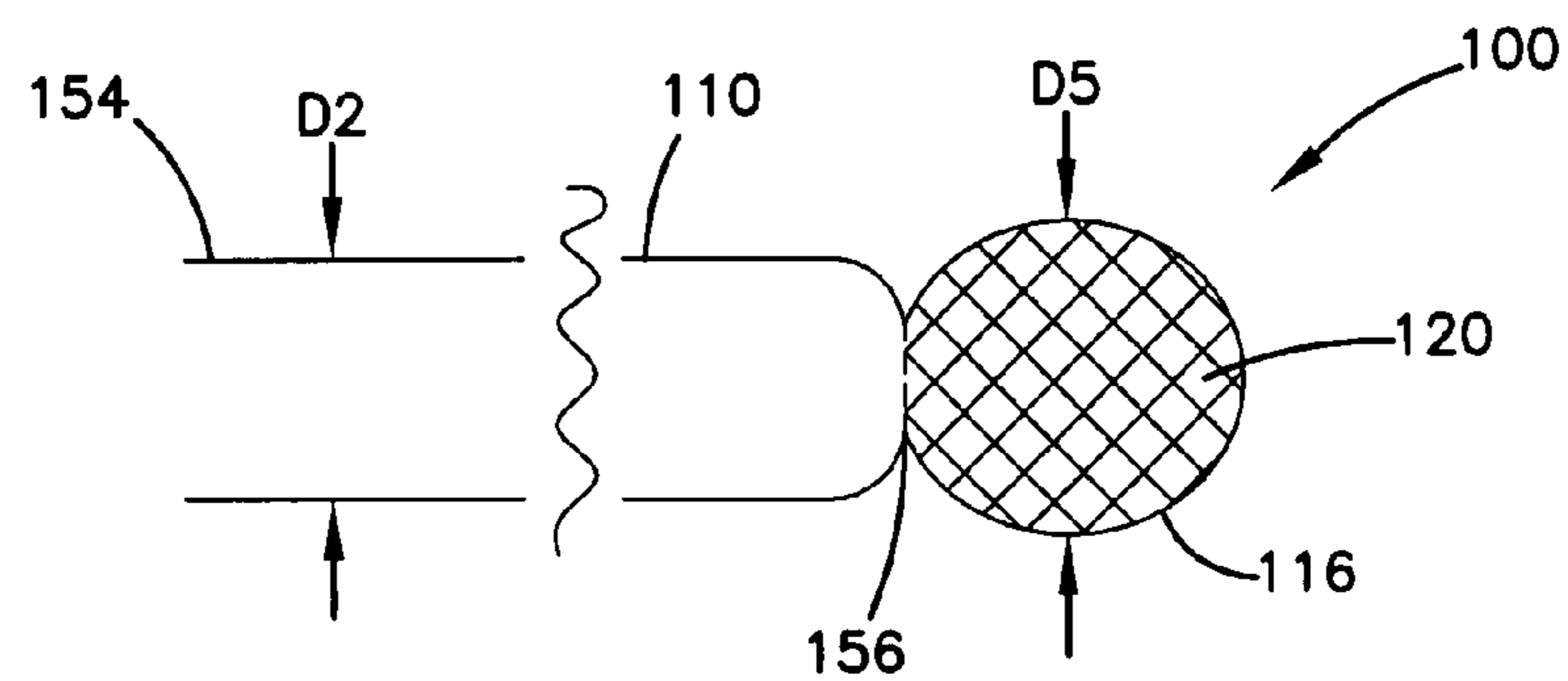


FIG. 6

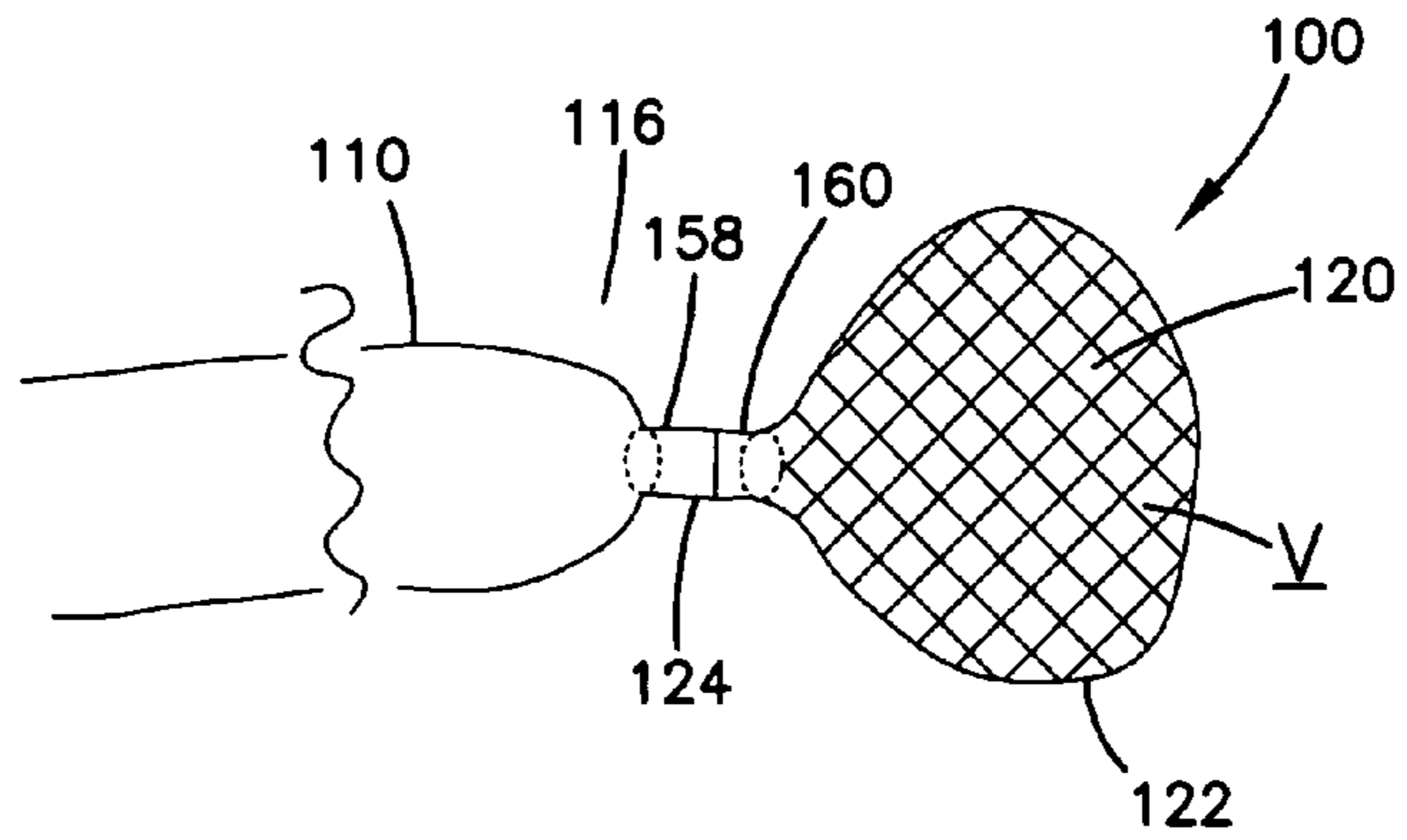


FIG. 7

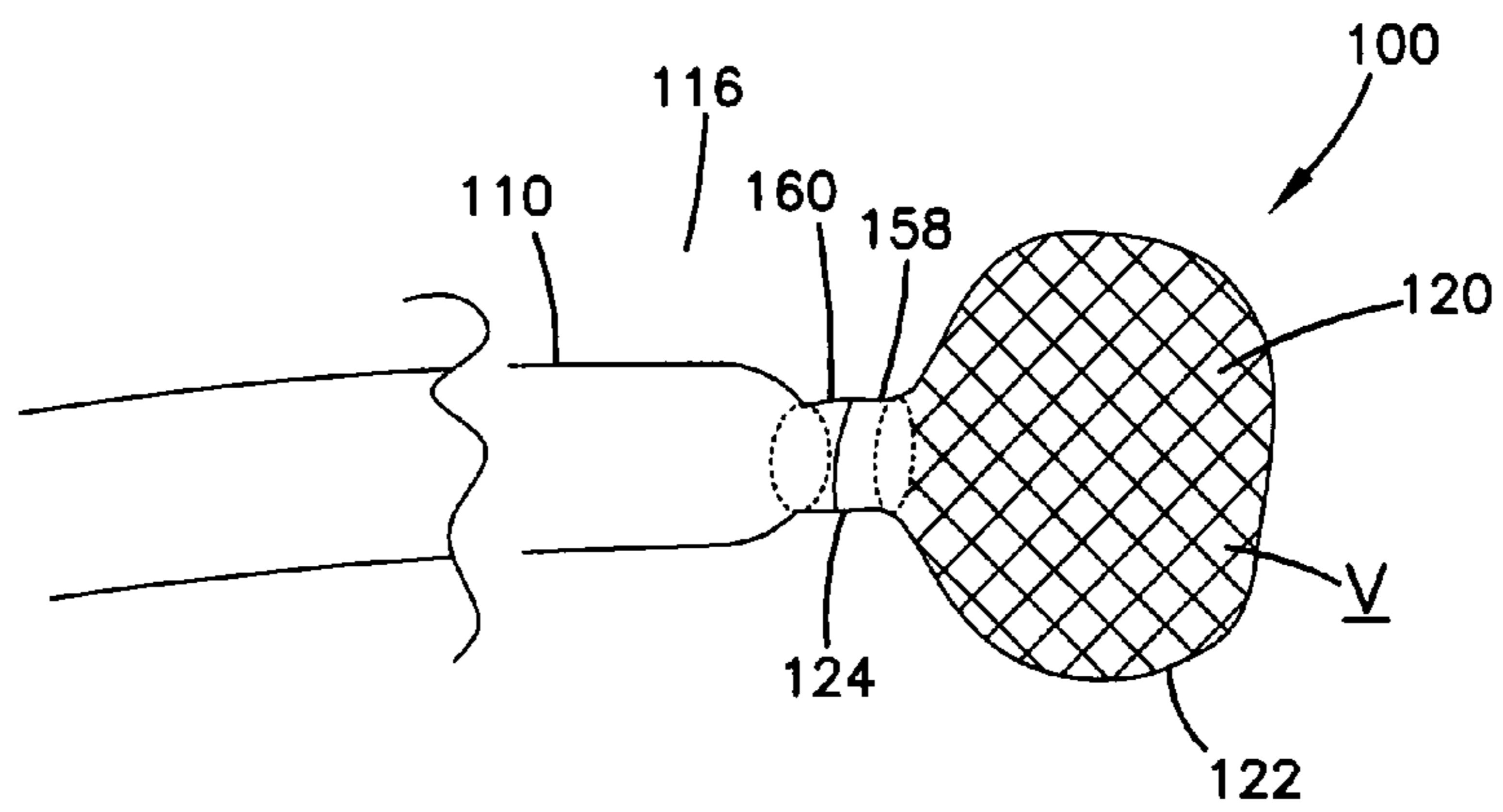


FIG. 8

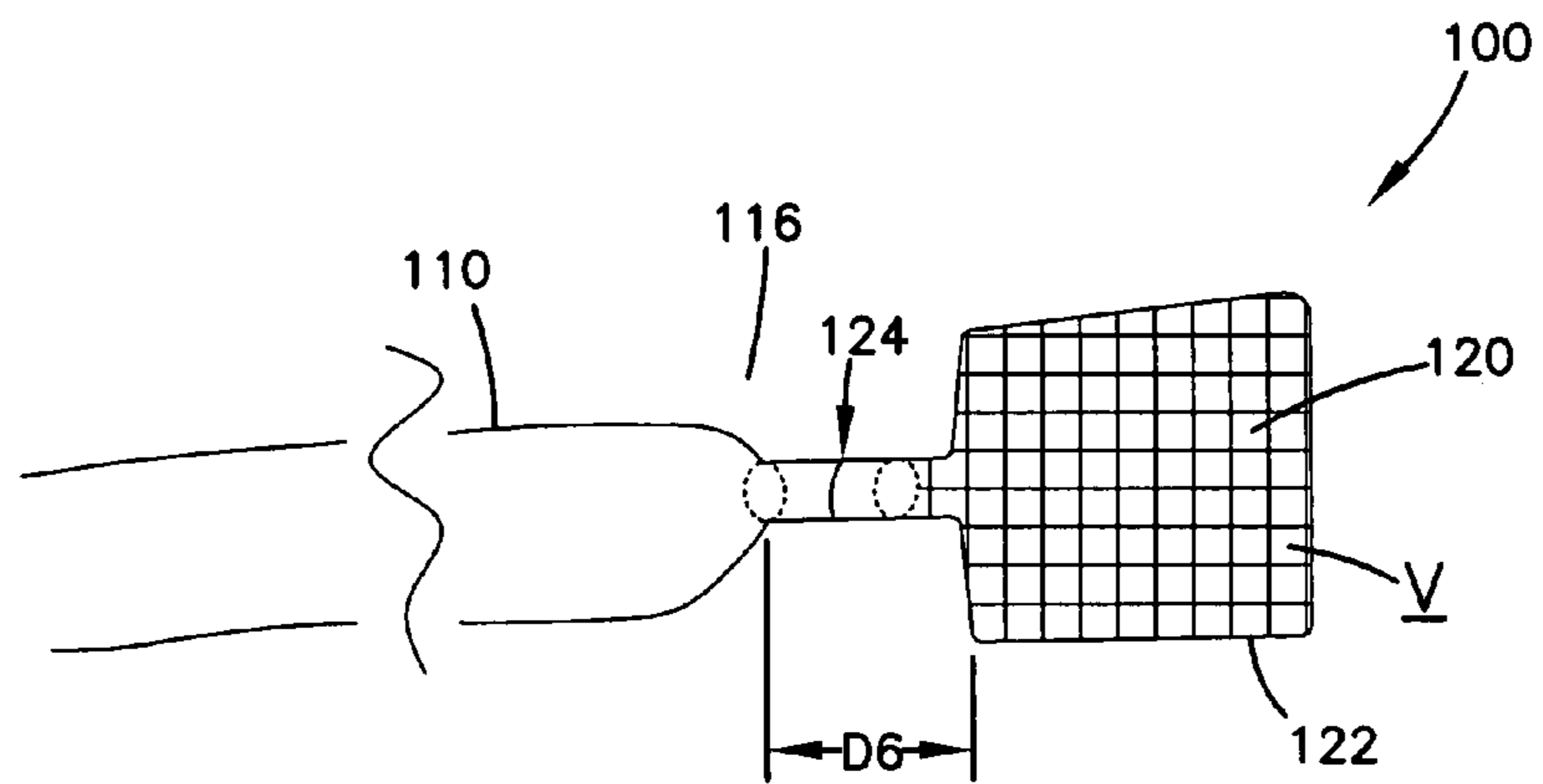


FIG.9

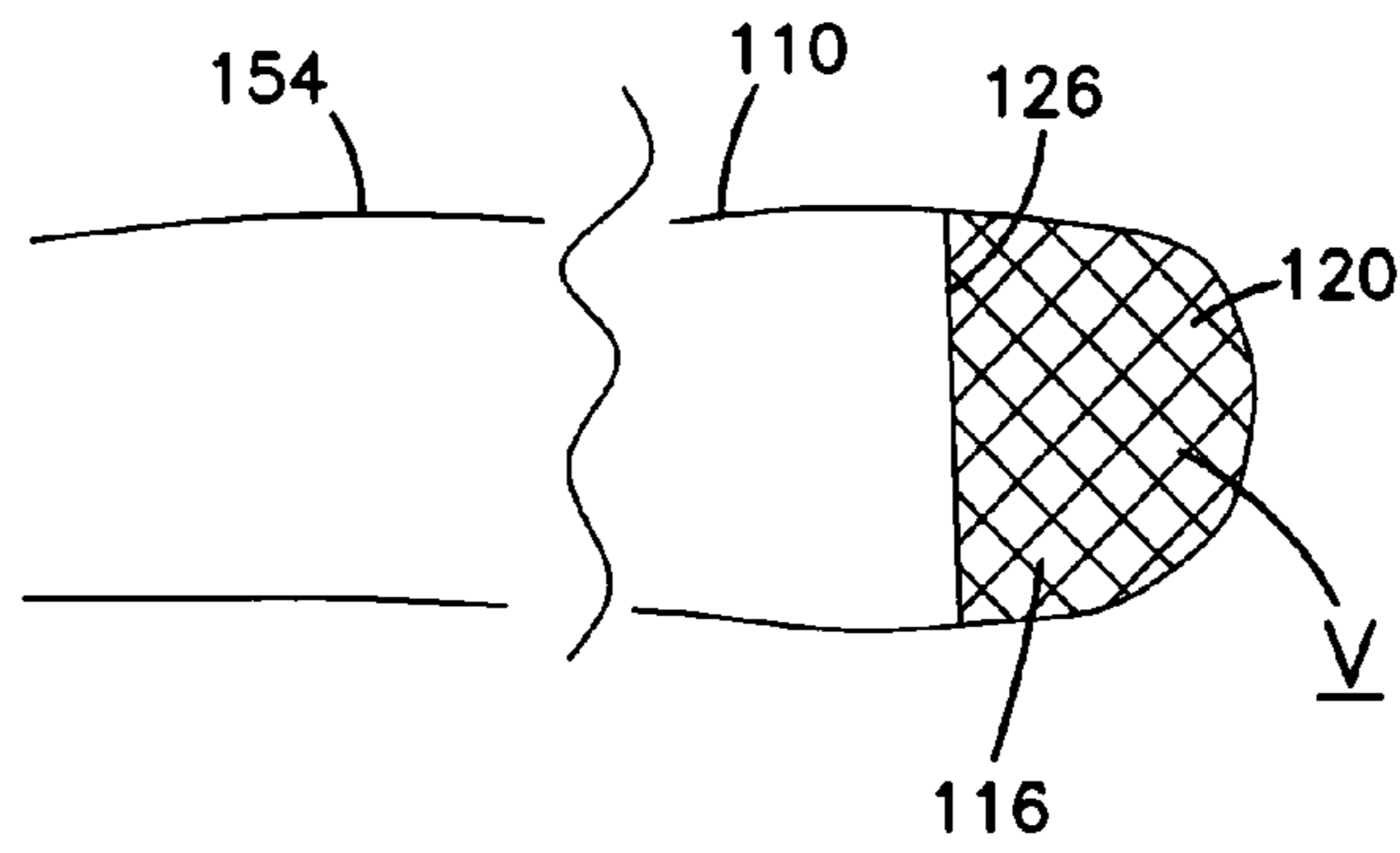


FIG.10

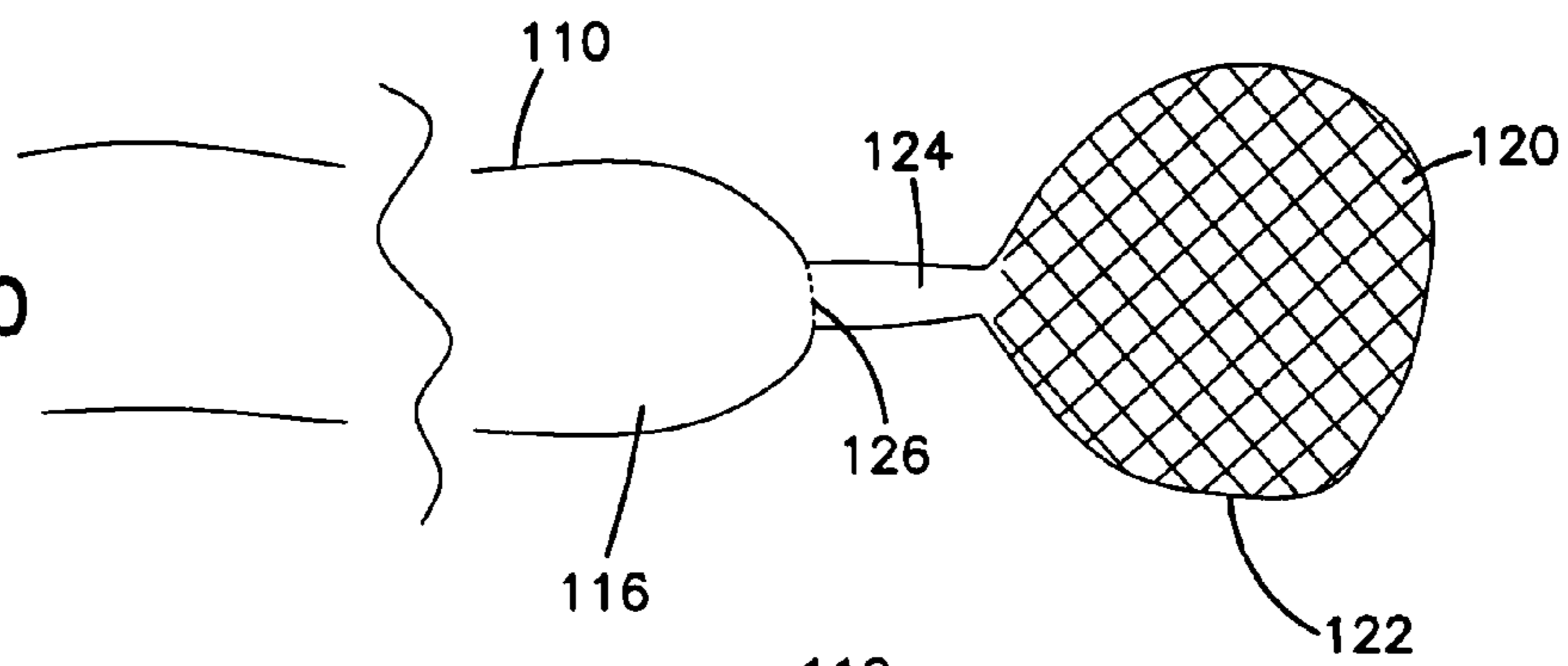


FIG.11

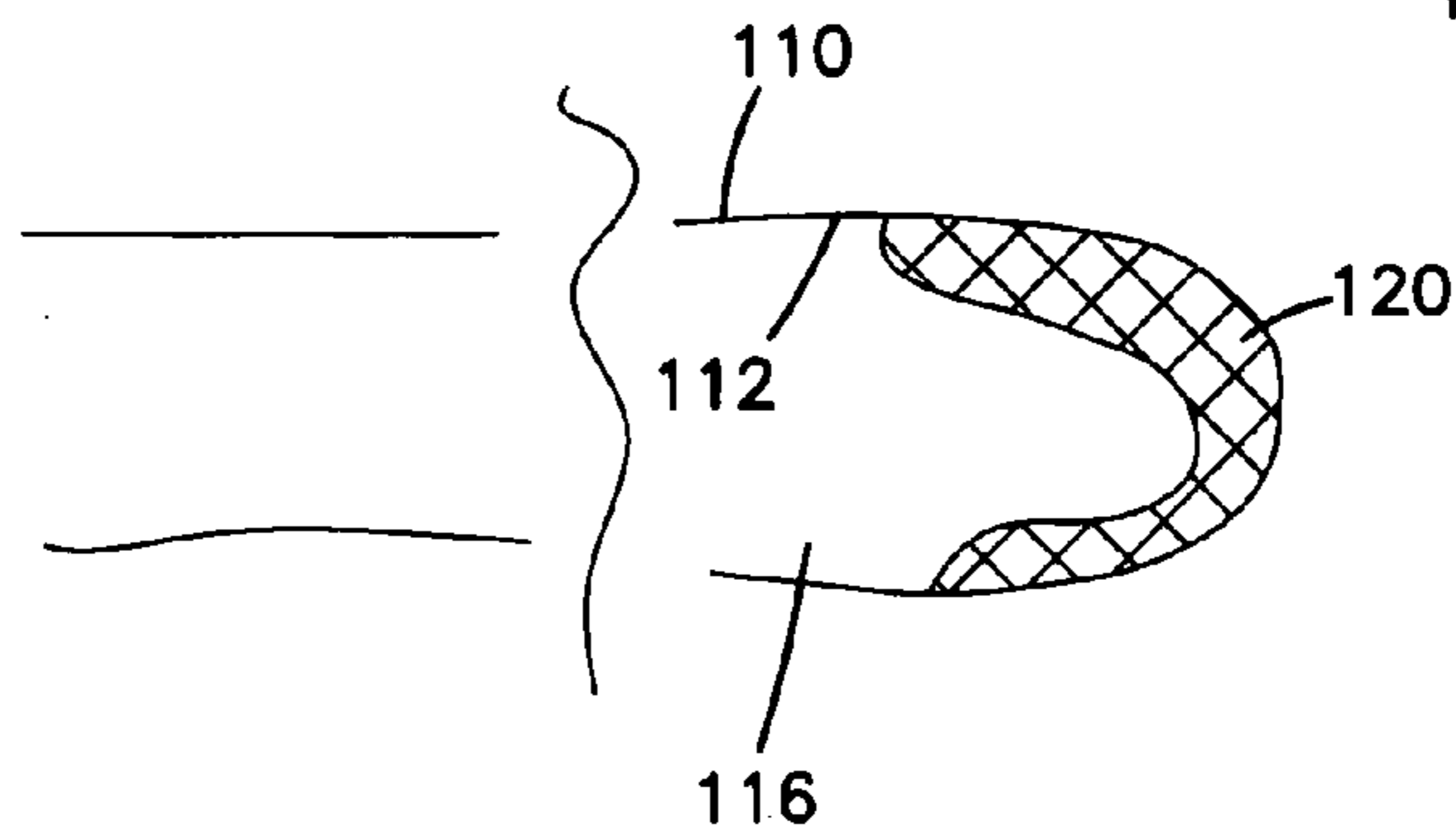


FIG.12

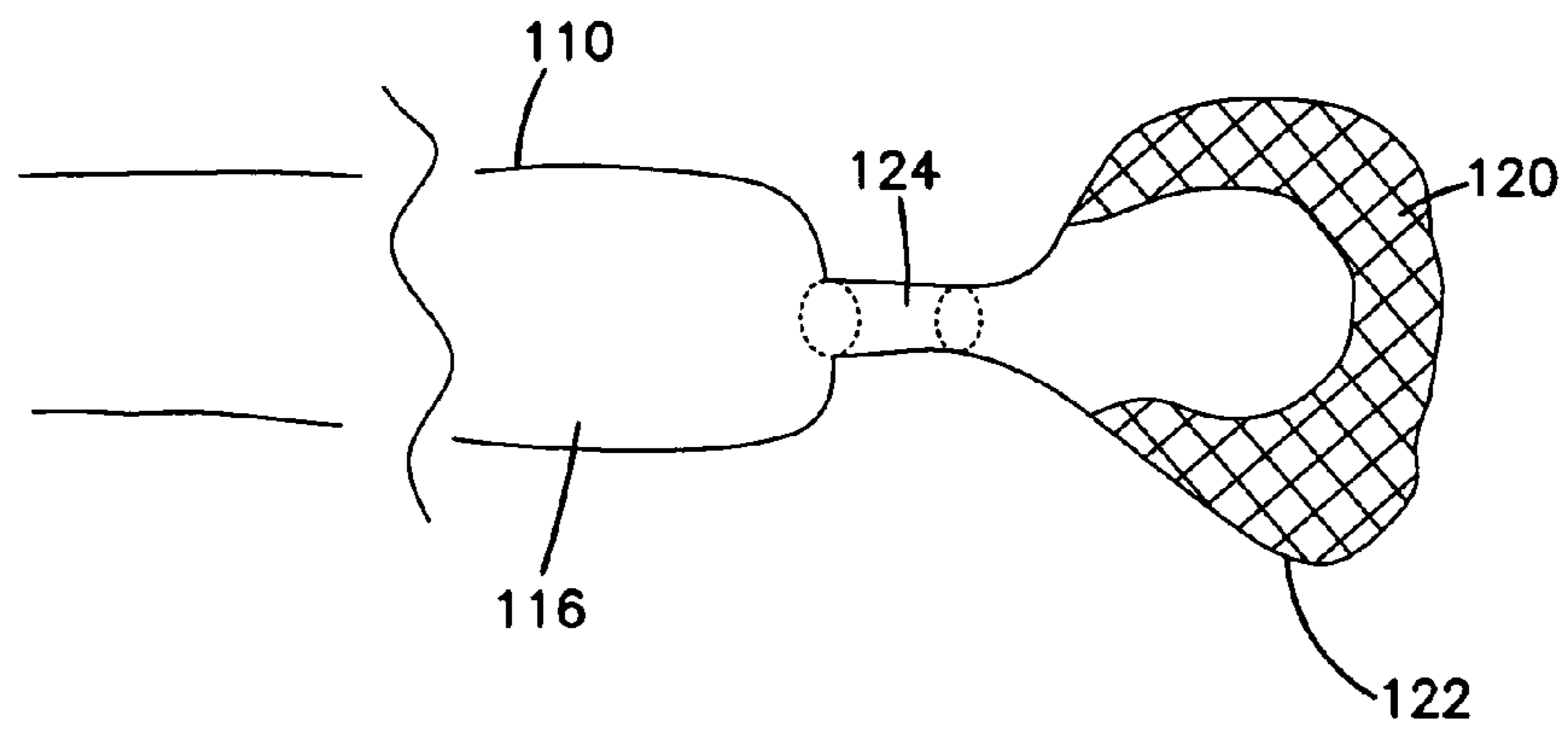


FIG.13

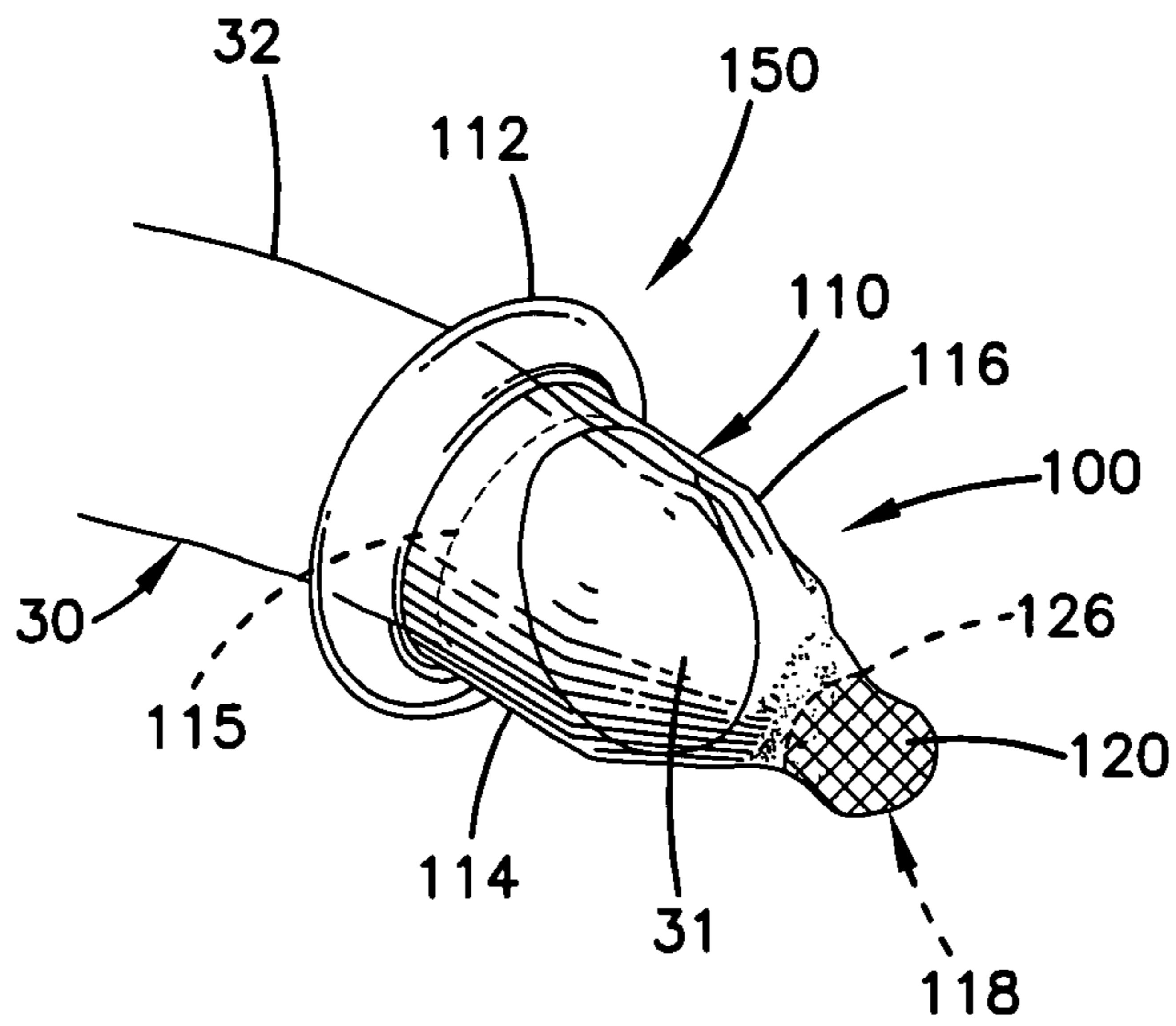
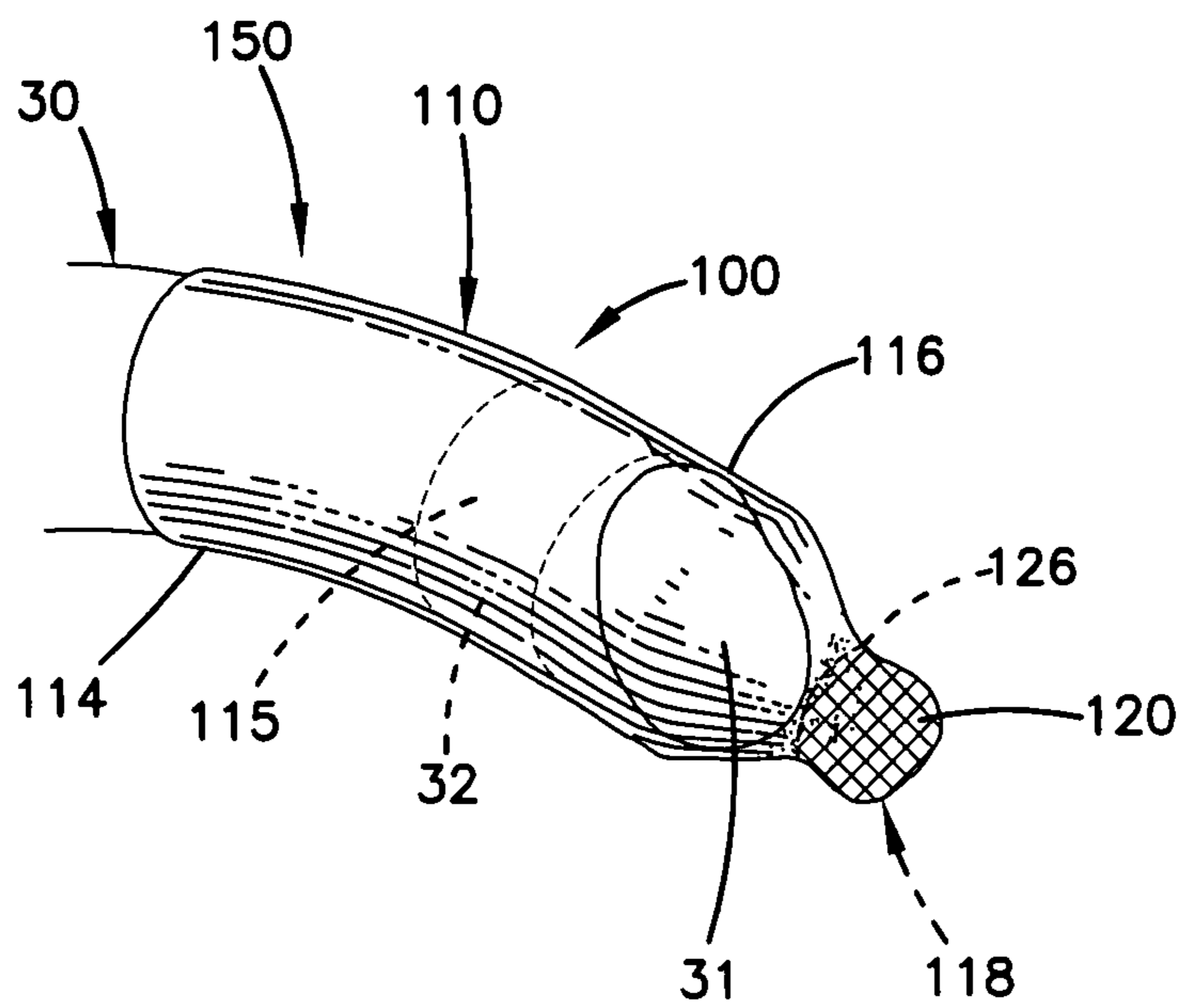
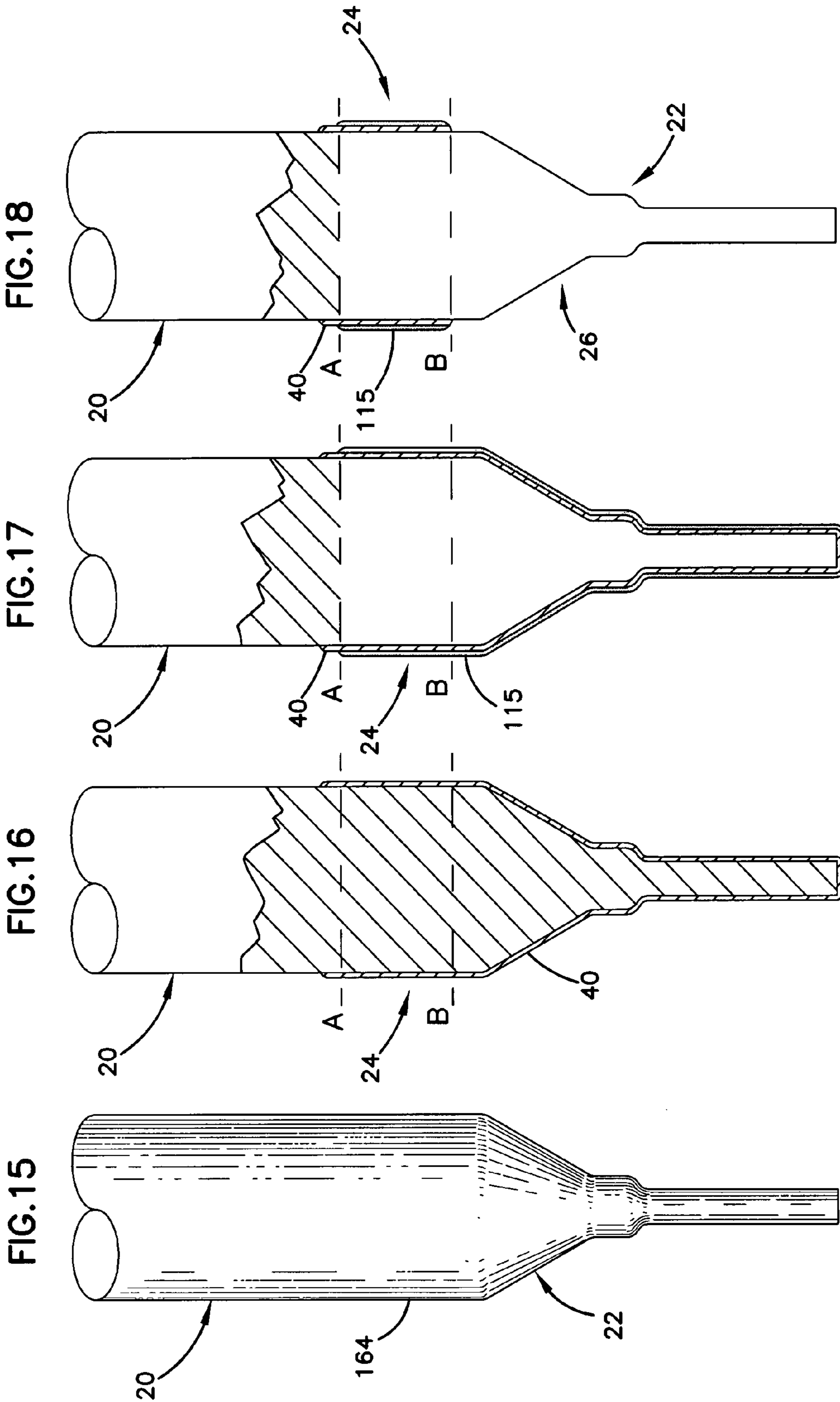
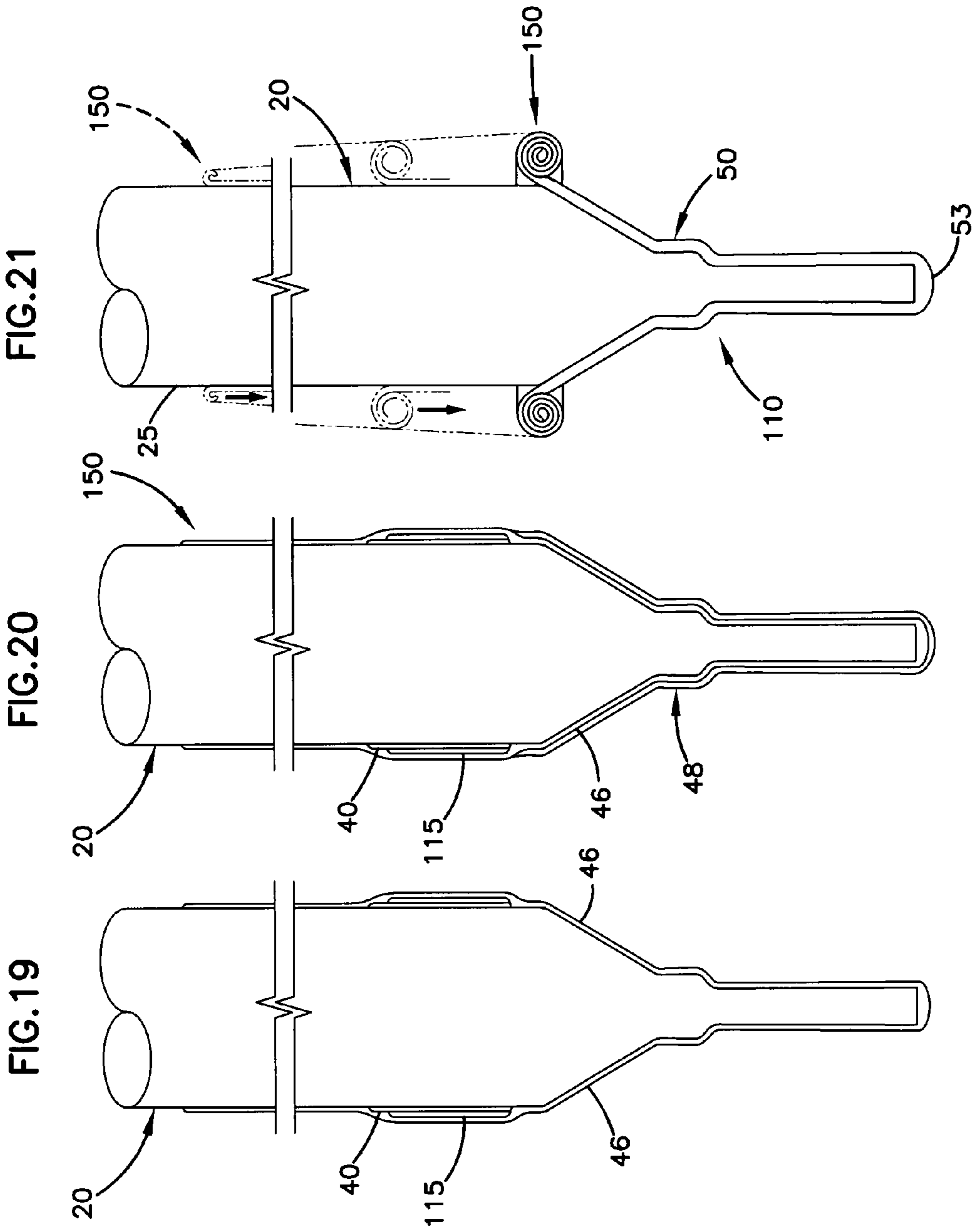
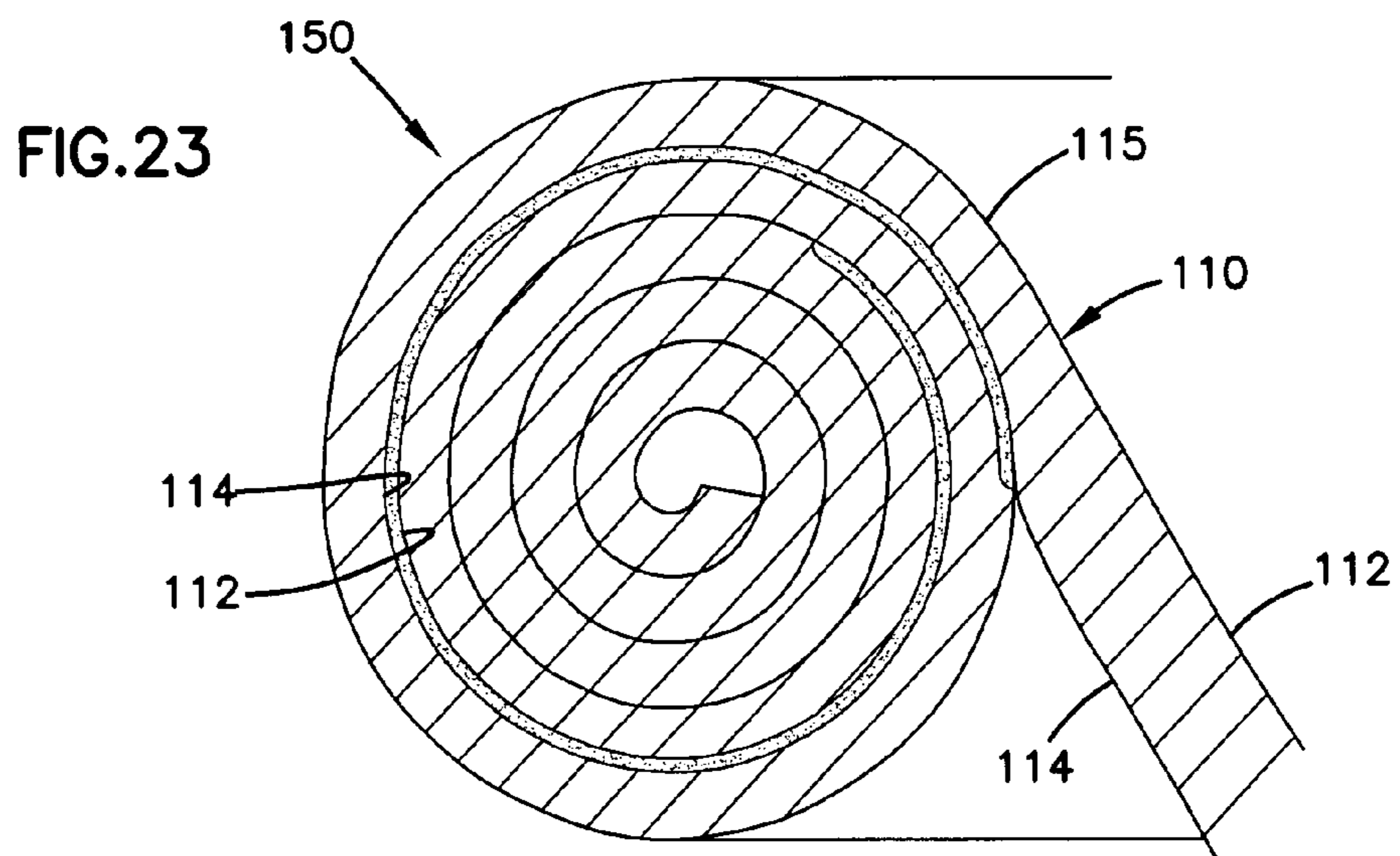
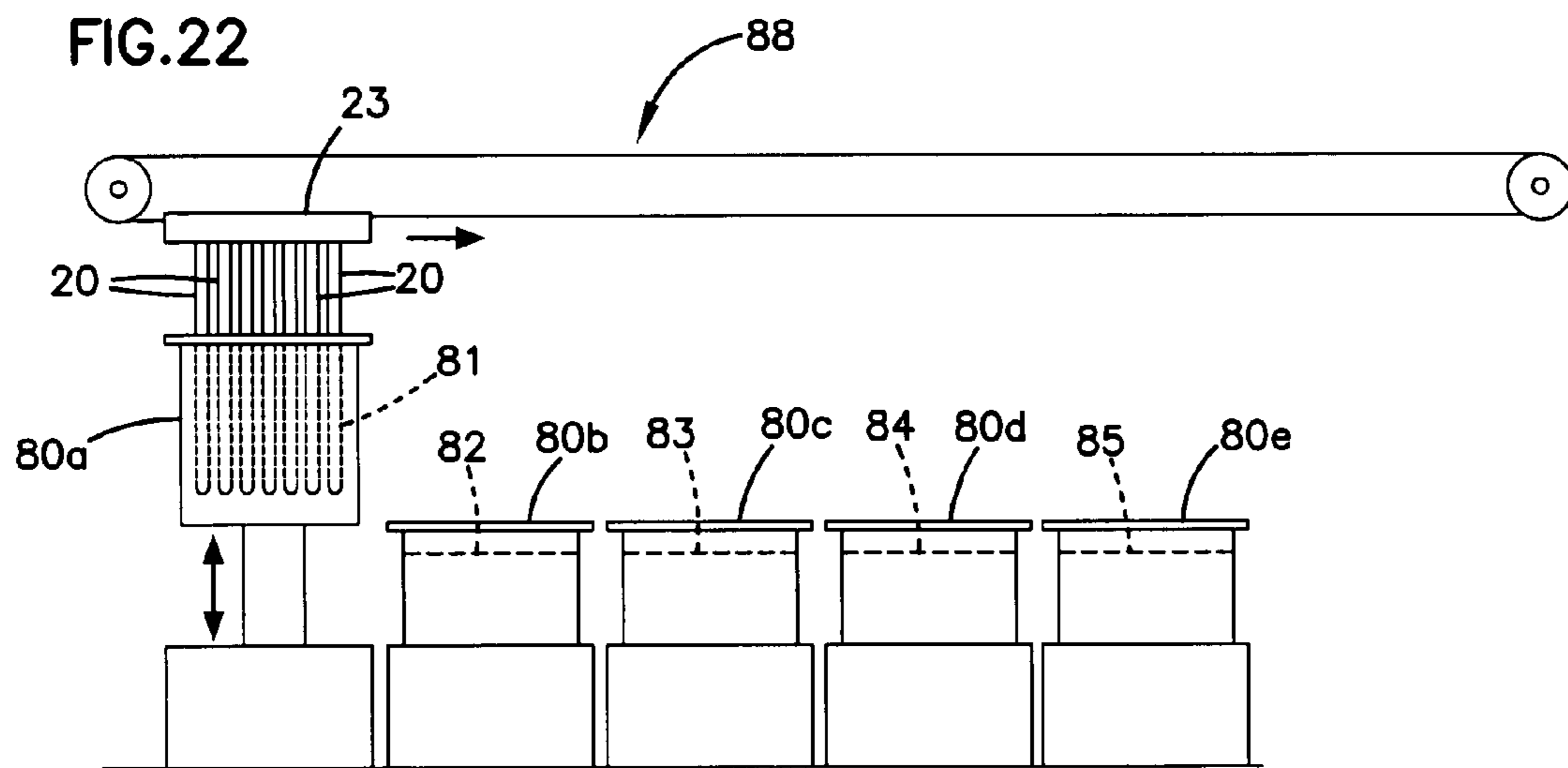


FIG.14

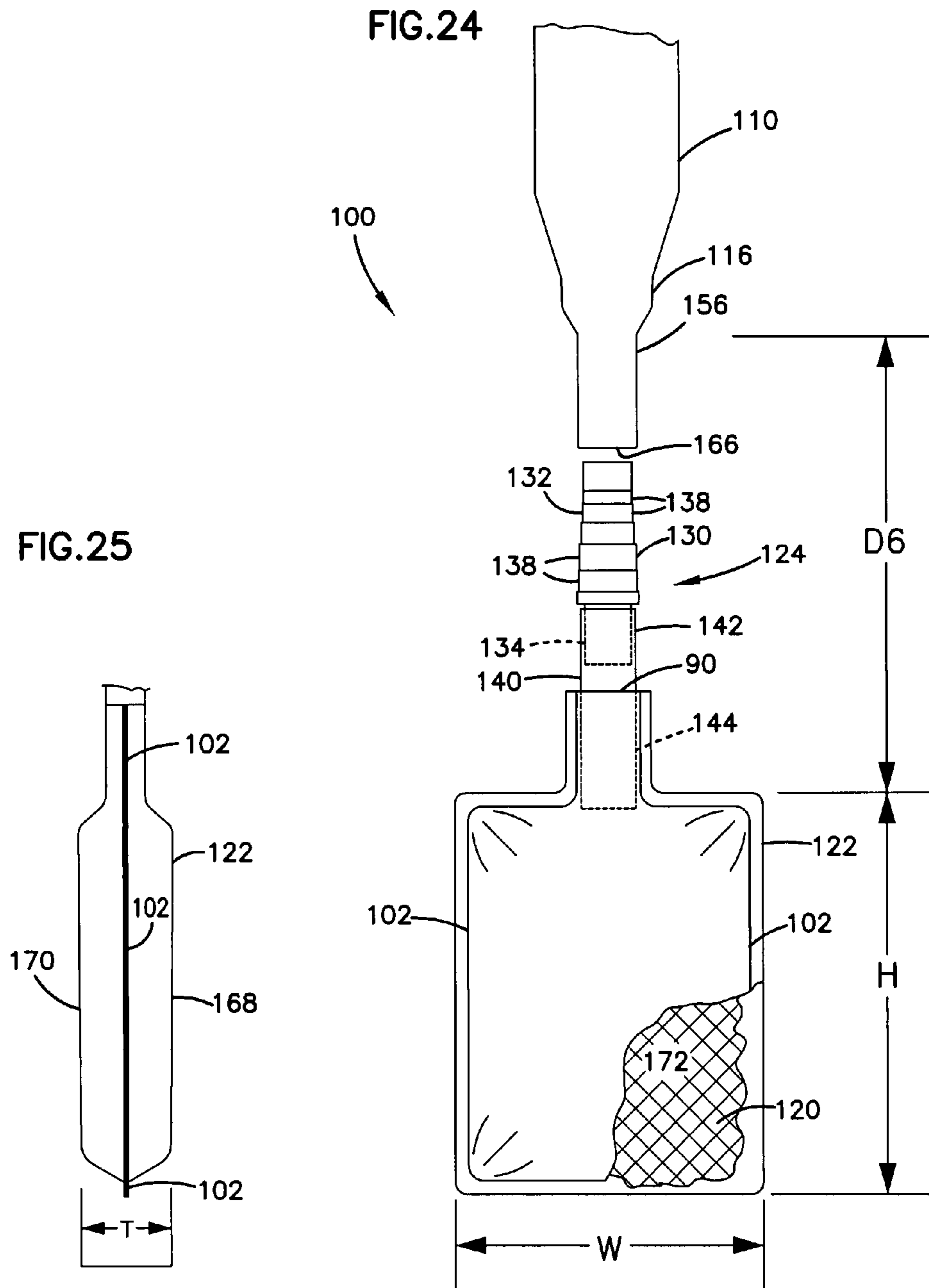












1

**SILICONE RUBBER MALE EXTERNAL  
CATHETER WITH ABSORBENT AND  
ADHESIVE**

TECHNICAL FIELD

The invention relates generally to external urinary catheters for males. More specifically, the invention relates to an external urinary catheter that includes an absorbent material to absorb urinary discharge.

BACKGROUND

Urinary incontinence can be a serious problem for men. Many incontinent men, particularly post prostatectomy patients, leak only small amounts of urine between normal voiding. Generally, male incontinence is handled through use of urine collection devices or absorbent pads. Urine collection devices include what is commonly called a "leg bag." A leg bag generally includes a tube and a large collection bag sized to collect an amount of urine typically discharged during voiding. The tube is retained near the urethra and extends to a location where the large collection bag resides. Often the large collection bag is strapped to the user's leg; hence the term "leg bag."

Existing remedies, although suited for individuals who leak a substantial volume of urine, are not well suited for an incontinent male that leaks only small volumes of urine between voiding. The existing devices are big, bulky, and uncomfortable. Other existing devices occlude leakage of urine, and are also uncomfortable. Some men will forego wearing such devices even though they suffer from urinary incontinence. Such men, and others using existing devices for the collection of only small amounts of urine, would benefit from a smaller, less bulky and more comfortable device that collects the small amounts of urine discharged between normal voiding.

Therefore, a need remains for a device that collects small amounts of urine leaked or discharged from incontinent males that does not necessarily occlude the leakage of urine and is not highly cumbersome to the user.

SUMMARY

The present disclosure relates to devices for management of male urinary incontinence, particularly for collecting small amounts of urine discharged between normal voiding. The present disclosure further relates to methods associated with the devices, including methods of use and manufacture. In one aspect of the present disclosure, the devices include male external urinary catheters that have an absorbent suitable for absorbing the small amounts of urine discharged between normal voiding.

A variety of examples of desirable device features or methods are set forth in part in the description that follows, and in part will be apparent from the description, or may be learned by practicing various aspects of the disclosure. The aspects of the disclosure may relate to individual features as well as combinations of features. It is to be understood that both the foregoing general description and the following detailed description are explanatory only, and are not restrictive of the claimed invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an enlarged cross sectional view of an external urinary catheter of the present invention shown in a pre-use orientation;

2

FIGS. 2 through 5 are cross sectional views of embodiments of the invention that have absorbent material in a distal end of the external urinary catheter;

FIGS. 6 through 8 are cross sectional views of embodiments of the invention that have absorbent material in a reversibly joined receptacle of the external urinary catheter;

FIGS. 9 and 10 are cross sectional views of embodiments of the invention that also include a semi-permeable barrier;

FIG. 11 is a cross sectional view of an embodiment of the invention that has the absorbent material adhered to an inner surface of a tubular sheath;

FIG. 12 is a cross sectional view of an embodiment of the invention that has the absorbent material adhered to the inner surface of the receptacle;

FIG. 13 is a perspective view of the external urinary catheter of FIG. 1 shown when the catheter is partially unrolled onto a penis;

FIG. 14 is a perspective view of the external urinary catheter of FIG. 13 shown when the catheter is fully unrolled onto the penis;

FIG. 15 is a side view of a mandrel used to form the tubular sheath of the external urinary catheter of the present invention;

FIG. 16 is a partial cross-sectional view of the mandrel of FIG. 15 shown when partially coated with a silicone coating;

FIG. 17 is a view similar to FIG. 16, but after the mandrel is partially coated with an adhesive layer;

FIG. 18 is a view similar to FIG. 17, but after a portion of the silicone coating and the adhesive layer on the mandrel have been stripped away;

FIG. 19 is a view similar to FIG. 18, but after a first overcoat layer of silicone rubber solution has been coated on the mandrel over the adhesive layer and silicone coating remaining on the mandrel;

FIG. 20 is a view similar to FIG. 19, but after an application of a second overcoat layer of a silicone rubber solution to a portion of the mandrel;

FIG. 21 is a view similar to FIG. 20, but after a step of curing or vulcanizing the tubular sheath, and showing an upper portion of the tubular sheath of the external urinary catheter rolled up;

FIG. 22 is a schematic illustration of a mechanized system used to coat the mandrels, as shown in FIGS. 15-21;

FIG. 23 is an enlarged cross-sectional view of the upper portion of the external urinary catheter of FIG. 1 in the pre-use orientation;

FIG. 24 is a top plan view of yet another embodiment of an external urinary catheter of the present invention; and

FIG. 25 is a side view of a portion of the external urinary catheter of FIG. 24.

DETAILED DESCRIPTION OF THE PREFERRED  
EMBODIMENT

Reference will now be made in detail to various features of the present disclosure that are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

I. Structural Description, Generally

Referring to FIG. 1, one embodiment of an external urinary catheter 100 is illustrated. The external urinary catheter 100 generally includes a tubular sheath 110, an adhesive layer 115, and absorbent material 120.

Following manufacture and during pre-use storage, the external urinary catheter 100 will generally have a pre-use orientation, as shown in FIG. 1. In the pre-use orientation, an

upper portion **150** of the tubular sheath **110** is rolled up as shown. The tubular sheath **110** of the catheter **100** has an inner surface **112** and an outer surface **114**. When the upper portion **150** is rolled up in the pre-use orientation, the inner surface **112** contacts the outer surface **114** of the tubular sheath **110**.

The adhesive layer **115** of the external urinary catheter **100** is provided on the inner surface **112** of the tubular sheath **110** during manufacture. Typically, the adhesive layer **115** includes a biocompatible adhesive. A biocompatible adhesive is an adhesive that can contact skin for extended periods without irritating or damaging the skin. Typically, the adhesive layer **115** is non-releasably bonded to a bonding region **152** of the inner surface **112**, as will be discussed in greater detail hereinafter. “Non-releasably bonded”, “non-releasable adherence”, or “non-releasable contact” refers to contact that does not permit easy separation of the adhesive layer **115** from the bonding region **152** of the tubular sheath **110**.

When the external urinary catheter **100** is in a pre-use orientation, the adhesive layer **115** is non-releasably bonded to the bonding region **152** of the inner surface **112**, and releasably bonded to the outer surface **114** of the tubular sheath **110**. “Releasably bonded”, “releasable adherence”, or “releasable contact” refers to contact that permits a relatively easy separation of the adhesive layer **115** from the outer surface **114** of the tubular sheath **110**. The adhesive layer **115** releases and separates from the outer surface **114** of the tubular sheath **110** when the upper portion **150** of the sheath **110** is unrolled, while the adhesive layer **115** remains non-releasably adhered to the bonding region **152** of the tubular sheath **110**.

Still referring to FIG. 1, the absorbent material **120** of the external urinary catheter generally functions to absorb leaked or discharged urine. As will be described in greater detail hereinafter, the absorbent material **120** can either be attached to tubular sheath **110** or simply contained within the tubular sheath **110**. In embodiments that simply contain the absorbent material **120**, it is contemplated that the absorbent material can be replaced or exchanged by the user without utilizing a different tubular sheath **110**.

General examples of suitable absorbent material include, but are not limited to: cotton fiber, cellulose fiber, absorbent polymers, hydrophilic absorbing power (powders having a chemical structure that hold moisture either intermolecularly or intramolecularly), synthetic fibers, and other types of material that absorb urine.

More specific examples of cellulose fibers include wood pulp, stabilized wood pulp, wood pulp with super absorbent, peat moss board, tissue paper, or creped wadding. More specific examples of synthetic fibers include nonwoven fibers of polypropylene, polyester, nylon, polyethylene, and copolymers thereof. One example of a suitable synthetic fiber is isotactic polypropylene.

More specific examples of absorbent polymers include polypropylene, polyacrylates such as sodium polyacrylate, and copolymers thereof. Absorbent polymers formed as a foam material can also be used. Such foam materials can be formed from the water actuation of polymers based on either toluene diisocyanate (TDI) or methylene diphenyl diisocyanate (MDI), for example. These polymers are commercially available under, for example, the trademarks “HYPOL” (TDI) and “HYPOL PLUS” (MDI) from W. R. Grace & Co., Organic Chemicals Division (Lexington, Mass.). Polymer foams can also be formed from polyurethanes or polyolefins.

The external urinary catheter **100** of the present disclosure may include various volumes or amounts of the absorbent material **120**. Generally speaking, the amount of absorbent material **120** used can be described by an actual volume of the absorbent, or by the volume of urine absorbed by the material.

The amount of absorbent material **120** included depends on the type of the absorbent material and the level of urinary discharge for which the catheter **100** is designed. For example, the amount of absorbent material **120** used for men that have higher levels of urinary discharge will be greater than the amount used for men that have lower levels of urinary discharge.

In general, the absorbent material **120** functions to absorb urine collected in the tubular sheath **110**. In the embodiment shown in FIG. 1, the absorbent material **120** is generally located in a distal end **116** of the tubular sheath **110**. There are a number of different configurations of the tubular sheaths **110** in which absorbent material **120** can be generally located in the distal end **116**. Examples of such alternative embodiments are shown in FIGS. 2-5.

Referring now to FIGS. 2-5, the distal end **116** of each of the tubular sheaths **110** has a different configuration. The different configurations of FIGS. 2-5 are only exemplary configurations; and other configurations are contemplated.

Referring specifically to FIG. 2, the distal end **116** of the tubular sheath **110** has a generally square shape with a cross-sectional dimension **D1**. The cross-sectional dimension **D1** is approximately equal to a diameter **D2** of a main portion **154** of the tubular sheath **110**. In an alternative embodiment, the cross-sectional dimension **D1** can be larger or smaller than the diameter **D2** of the remainder of the tubular sheath **110**.

In FIG. 3, the distal end **116** of the tubular sheath **110** has a generally rounded shape with a maximum diameter **D3**. The maximum diameter **D3** is approximately the same as that of the main portion **154** of the tubular sheath **110**. In FIG. 4, the distal end **116** has a generally round shape with a maximum diameter **D4**. The maximum diameter **D4** is greater than that of the main portion **154** of the tubular sheath **110**.

In FIG. 5, the distal end **116** has a generally round shape with a maximum diameter **D5** that is also greater than the diameter **D2** of the main portion **154** of the tubular sheath **110**. However, in FIG. 5, the distal end **116** includes a necked portion **156** that reduces in diameter prior to expanding to the maximum diameter **D5**. In an alternative embodiment, the tubular sheath **110** can include a necked portion that expands to a maximum diameter **D5** that is less than the diameter **D2** of the main portion **154**. It should also be understood that any combinations of these and other distal end constructions and shapes could be utilized. For example, the distal end **116** can have a necked portion, and include a generally square shape with a dimension greater than or less than the main portion **154** of the tubular sheath **110**.

Referring now to FIGS. 6-8, in alternative embodiments, the absorbent material **120** can be located in a receptacle **122** (e.g. a pouch or cartridge). (See also FIG. 24.) Typically, the receptacle **122** is interconnected to the distal end **116** of the tubular sheath **110** by a joining assembly **124**.

The receptacle **122** can be fashioned from a material that is one or more of pliable, durable, collapsible, and inexpensive. For example, the receptacle **122** can be pliable so that the catheter **100** is more malleable and comfortable for a user. The receptacle **122** can be durable to limit the possibility of the receptacle **122** being pierced or ruptured. The receptacle **122** can be inexpensive so that the receptacle **122** can be replaced whenever appropriate without excessive cost. Examples of suitable materials that can be used to manufacture the receptacle **122** include, for example, polyvinyl chloride (PVC), polyurethane, block copolymers such as kraton, high density polyethylene, low density polyethylene, and silicone rubber. As can be understood, the receptacle **122** is in certain embodiments waterproof (i.e., not permeable to water over the length of time that the receptacle will remain in the

user's undergarment). The material can have a waterproof quality, or a waterproofing material can be applied during the manufacture of the receptacle **122**.

Generally, the thickness of receptacle **122** (i.e., the dimension that would be shown in a side view of FIG. 6-8) varies depending on the type of material used, and the type and amount of absorbent material **120** used. Typically, the thickness of receptacle **122**, including the absorbent material **120**, ranges from about 0.125 inches to about 1.50 inches; more typically between about 0.125 inches and 0.750 inches. Preferably, the thickness of the receptacle **122** is sized to be comfortable and concealable.

The capacity of the receptacle **122** varies depending on the level of urinary discharge for which the specific embodiment is designed. Embodiments designed for higher levels of urinary discharge will have receptacles **122** with a higher capacity, while those designed for lower levels of urinary discharge will have receptacles **122** with a lower capacity. The capacity of the receptacles **122** can be smaller than a leg bag and suitable for receiving discharge between voiding. Typically, the receptacle **122** has a capacity or volume *V* from about 25 mL to about 100 mL. Generally speaking, if the receptacle **122** is designed for higher levels of urinary discharge, the receptacle has a volume *V* of about 40 to 100 mL. If the receptacle **122** is designed for lower levels of urinary discharge, the receptacle has a volume *V* of about 25 to 35 mL.

The shape of receptacle **122** can vary. Exemplary configurations of the receptacle **122** are illustrated in FIGS. 6-8. As shown, the receptacle **122** can have virtually any shape, including a generally round shape (FIGS. 6 and 7) and a generally square shape (FIG. 8).

Embodiments that include the receptacle **122** can be designed so that receptacles of variable capacity can be used interchangeably. This feature allows a user to vary the capacity of the external urinary catheter **100** based on a personal level of urinary discharge, which may or may not vary. For example, in one embodiment, a kit may be provided to a user. The kit may include a tubular sheath **110** along with an array of receptacles **122**. Each receptacle provided would include a different amount of absorbent material contained within the receptacle. This would permit the user to adjust the capacity of the external urinary catheter **100** according to the daily needs of the user.

In use, discharged urine flows from the sheath **110**, through the joining assembly **124**, and into the receptacle **122**. The joining assembly **124** of the external urinary catheter **100** functions to reversibly join the receptacle **122** to the distal end **116** of the tubular sheath **110**. What is meant by "reversibly join" is that the receptacle **122** sealingly attaches to the tubular sheath **110**, yet is detachable or removable from the sheath without causing damage to the sheath.

The joining assembly **124** is sized and constructed such that the receptacle **122** is located a distance near the distal end **116** of the tubular sheath **110**, as opposed to a leg bag which is located a distance away from the tubular sheath **110**. Typically, the receptacle **122** is located in relation to the tubular sheath **110** such that the entire catheter **100**, including the receptacle **122**, is located at and within the pelvic region of the user. That is, the tubular sheath **110**, the joining assembly **124**, and the receptacle **122** can all fit within a user's undergarment at the urinary area. The user is thereby not encumbered with routing tubes through the undergarment to locations away from the urinary area, such as is required by conventional leg bags, for example. In the illustrated embodiment, the receptacle **122** is located a distance *D6* (e.g. FIG. 8) of about one inch to about three inches from the distal end **116** of the tubular sheath **110**.

In the embodiment of FIG. 6, the joining assembly **124** includes a female connector **158** extending from the distal end **116** of the tubular sheath **110**, and a male connector **160** extending from the receptacle **122**. In the embodiment of FIG. 7, the female connector **158** of the joining assembly **124** extends from the receptacle **122**, and the male connector **160** extends from the distal end **116** of the tubular sheath **110**. In each embodiment, the male connector **160** fits within the female connector **158** so that the tubular sheath **110** is reversibly joined to the receptacle **122**.

In another embodiment, the joining assembly **124** can include a lock and unlock feature so that receptacle **122** is more securely reversibly joined to tubular sheath **110**. In yet another embodiment, the joining assembly **124** functions like or includes a luer lock type assembly. As shown in FIGS. 6-8, the size of joining assembly **124** can vary. For example, in FIG. 7, the joining assembly **124** is larger than the joining assemblies shown in FIGS. 6 and 8. In an embodiment, the joining assembly **124** is large enough so that urine flow into the receptacle **122** is not restricted.

Referring now to FIGS. 24 and 25, another alternative embodiment of the external urinary catheter **100** is illustrated. Similar to some of the previous embodiments, the tubular sheath **110** of this embodiment is interconnected to the receptacle **122** via the joining assembly **124**.

As shown in FIG. 24, the distal end **116** of the tubular sheath **110** defines an opening **166** that receives the joining assembly **124**. The joining assembly **124** provides fluid communication between the tubular sheath **110** and the receptacle **122**. The opening **166** is located in the tapering or necked portion **156** of the tubular sheath.

The joining assembly **124** in the illustrated embodiment includes a hollow fitting **130** and a tube member **140**. In an embodiment, each of the hollow fitting **130** and the tube member **140** of the joining assembly **124** is sized so that urine flow into the receptacle **122** is not restricted.

The hollow fitting **130** has first and second ends **132**, **134**. Each of the first and second ends **132**, **134** is a male fitting end. The first male fitting end **132** is sized and constructed for receipt within the opening **166** formed in the distal end **116** of the tubular sheath **110**. In the illustrated embodiment, the first male fitting end **132** includes ridges **138** that taper to ease insertion and removal of the fitting **130** into and from the opening **166**. Other embodiments may include a first end **132** that continuously tapers without ridges, or that has a straight fitting construction.

The second male fitting end **134** is received within a first end **142** of the tube member **140**. In the illustrated embodiment, the second male fitting end **134** is secured within the first end **142** of the tube member **140** by an adhesive or other securing material or construction. In the illustrated embodiment, the second male fitting end **134** is a straight fitting end. Other embodiments may include a second end **134** that continuously tapers or includes ridges.

A second end **144** of the tube member is positioned within an opening **90** formed in the receptacle. In the illustrated embodiment, the second end **144** of the tube member **140** is secured within the opening **90** of the receptacle **122** by an adhesive or other securing material or construction.

In the embodiment shown in FIGS. 24 and 25, the receptacle **122** is constructed from a material that is pliable and durable, such as PVC, for example. In particular, first and second sheets or plies **168**, **170** of the material are joined together to form an interior **172** for receipt of the absorbent material **120**. In one embodiment, the two plies may be sewn together along a seam **102**, or adhered together along the seam. The PVC receptacle **122** also has sufficient pliability so

that the catheter **100** is more malleable and more comfortable for a user. In addition, the PVC receptacle **122** is durable to limit the possibility of the receptacle **122** being pierced or ruptured. Further, the PVC receptacle has moisture impermeable qualities that contain moisture absorbed by the absorbent material **120** within the interior **172** of the receptacle **122** so that the exterior of the receptacle **122** remains dry.

As shown in FIGS. **24** and **25**, the receptacle **122** generally has a width *W*, a height *H*, and a thickness *T*, although the disclosed principles can be applied in a variety of sizes and applications. The width *W* of the receptacle **122** can be, for example, between 1.5 and 5.0 inches or between about 2.0 and 3.0 inches. The height *H* of the receptacle **122** can be, for example, between 2.0 inches and 6.0 inches or between about 3.0 and 4.0 inches. The thickness *T* of the receptacle **122** is generally between 0.125 inches and 1.50 inches, depending upon the type of absorbent material **120** used. In an embodiment, the thickness *T* is between about 0.5 and 1.0 inches. Further, the distance *D6* (see FIG. **6**) between the receptacle **122** and the distal end **116** of the tubular sheath **110** when assembled (not shown) can be between 2.0 inches and 6.0 inches; e.g., between about 3.5 and 4.5 inches.

Each of the width *W*, the height *H*, the thickness *T*, and the distance *D6* are sized and dimensioned such that the receptacle **122** conveniently fits within the undergarment of the user. That is, the receptacle **122** is sized so that the entire catheter **100** fits within the user's underwear, and does not require that the receptacle be attached or located at a location away from the pelvic area of the user. Accordingly, the PVC material of the receptacle **122** is also chosen to be comfortable against the user's skin. For example, the exterior of the receptacle **122** can be flocked with cotton or synthetic flocking, or embossed. As previously discussed, the shape of receptacle **122** can vary. In the embodiment of FIGS. **24** and **25**, the receptacle **122** has a rectangular configuration, although any shape that comfortably fits an average-sized male can be used.

At the same time, the receptacle **122** is sized to provide a urine absorbing capacity depending on the level of urinary discharge between normal voiding. As previously described in relation to the other embodiments, the capacity of the receptacle **122** of FIG. **24** can be smaller than a leg bag and suitable for receiving discharge between voiding. The width *W*, height *H*, and thickness *T* of the receptacle **122** defines a volume associated with the receptacle **122**. The capacity of the receptacle **122** is a function of the volume and the type of absorbent material **120** used. In an embodiment, the volume of the receptacle **122** is between 1.0 cubic inch and 5.0 cubic inches. In one embodiment, the absorbent material **120** is cellulose fiber. In providing cellulose fiber absorbent material in the volume of between about 3.0 and 4.0 cubic inches, the receptacle **122** has a capacity to contain between about 45 and 60 mL of urine. Because the receptacle **122** is sized to fit within the user's pelvic region, (i.e., within the user's undergarment) the capacity of the receptacle **122** is typically no more than about 100.0 mL.

Similar to the previous embodiments, the embodiment of FIG. **24** is designed so that the receptacle **122** can be interchanged. This feature allows a user to vary the capacity of the external urinary catheter **100** based on a personal level of urinary discharge, which may or may not vary. For example, a user may interchange a first receptacle with a second receptacle having a different amount of absorbent material or a different type of absorbent material to adjust the capacity of the external urinary catheter **100**.

The receptacle **122** is also interchangeable so that a user can replace a filled or used receptacle with a new receptacle as needed. For example, during use of the catheter **100** embodi-

ment of FIG. **24**, urine discharged into the sheath **110** flows through the joining assembly **124** and into the receptacle **122**. When the receptacle **122** has filled, the user detaches the filled receptacle by removing the first end **132** of the fitting **130** from the opening **166** in the tubular sheath **110**. The tubular sheath **110** remains in position on the penis. A new receptacle is then attached to the distal end **116** of the tubular sheath.

The joining assembly **124** of the external urinary catheter **100** functions to reversibly join the receptacle **122** to the distal end **116** of the tubular sheath **110**. In the embodiment of FIG. **24**, the joining assembly **124** attaches and detaches from the tubular sheath **110** (i.e., the joining assembly **124** is removed or detached along with the receptacle **122**). In an alternative embodiment, the catheter **100** can be constructed such that the receptacle **122** attaches and detaches from the joining assembly **124** (i.e., only the receptacle **122** is removed or detached).

The receptacle **122** can also be disposable. The user may simply throw away the receptacle when the receptacle has been filled. In alternative embodiments, the receptacle **122** may be recycled. That is, the receptacle can be configured to provide access to the absorbent material **120** so that used absorbent material can be removed and replaced with new material, and the receptacle **122** reused.

Various alternative embodiments including other features can be practiced in accord with the principles disclosed. For example, the external urinary catheter **100** may include more than one type of absorbent material **120**. For instance, a synthetic fiber such as polypropylene, polyester, nylon, polyethylene, or copolymers thereof can be spunbound to create a coverstock for another absorbent. A coverstock functions to provide a semi-permeable membrane or barrier that allows moisture to pass through that barrier so that the moisture is absorbed by another absorbent material enclosed within the barrier. Use of a coverstock provides a number of advantages, including keeping the skin of the user more dry, and retaining the absorbent material **102** in a particular location, such as a distal end **116** of the tubular sheath **110**. Suitable examples of synthetic fibers that can be spunbound to form coverstock include polyester and polypropylene.

Referring now to the external urinary catheters **100** of FIGS. **9** and **10**, two embodiments of a coverstock or semi-permeable barrier **126** are illustrated. In the embodiment of FIG. **9**, the semi-permeable barrier **126** is located adjacent to the distal end **116** of the tubular sheath **110**. In the embodiment of FIG. **10**, the semi-permeable barrier **126** is in the joining assembly **124**.

The semi-permeable barrier **126** functions to allow urine to pass into the absorbent material **120**, but does not allow the absorbent material **120** to migrate through to the main portion **154** of the tubular sheath **110**. Alternatively, or in addition, the semi-permeable barrier **126** can function to allow urine to pass through into the volume *V* containing the absorbent material **120**, but does not allow urine to pass out of the volume *V*. In an embodiment in which the absorbent material **120** is completely contained or surrounded by the barrier **126**, the barrier **126** and the absorbent material **120** can be replaced or exchanged by the user without utilizing another tubular sheath **110**. For example, as shown in FIGS. **13** and **14**, the barrier **126** and absorbent material **120** can be provided in the form of a packet **118**. The packet **118** can be replaced and exchanged without utilizing another tubular sheath **110**. It is to be understood that the semi-permeable barrier can be incorporated into any of the embodiments shown, and in combination with any other features described.

Another alternative embodiment including another feature that can be practiced in accord with the principles disclosed is illustrated in FIG. **11**. In this embodiment the absorbent mate-

rial 120 of the external urinary catheter 100 is adhered to the inner surface 112 of the tubular sheath 110. Adhering the absorbent material 120 to the inner surface 112 prevents the absorbent material 120 from migrating within the tubular sheath 110. Methods of adhering the absorbent material 120 to the inner surface 112 of the tubular sheath 110 vary depending on the composition of the absorbent material 120. The absorbent material 120 can also be adhered to the inner surface of the receptacle 122, as shown in FIG. 12. It is to be understood that adhering the material to an inner surface can be incorporated into any of the embodiments shown, and in combination with any other features described.

## II. Method of Use

The external urinary catheter 100 is typically worn by users that discharge relatively small amounts of urine between normal voiding, as compared to users that discharge an amount that necessitates a leg bag. Referring to FIGS. 13 and 14, in use, a user, or perhaps a health care professional, engages a tip 31 of a penis 30 with the external urinary catheter 100 in the pre-use orientation (shown in FIG. 1). In particular, the distal end 116 of the tubular sheath 110 is applied to the tip 31 of the penis 30. The upper portion 150 of the tubular sheath 110 is then unrolled using moderate force to press the rolled up portion of the upper portion 150 in a direction away from the tip 31 of the penis 30. This can generally be accomplished by pressing on the rolled upper portion 150 with one's thumb and forefinger (not shown).

As the upper portion 150 unrolls, the adhesive layer 115 releases from the outer surface 114 of the tubular sheath 110. In an embodiment, the releasability characteristics are such that the upper portion 150 is relatively easy to unroll onto the penis 30. As the adhesive layer 115 comes into contact with an outer surface 32 of the penis 30, the adhesive layer 115 adheres to the outer surface 32. This secures the external urinary catheter 100 to the penis 30. In an embodiment, the adhesive layer 115 seals the tubular sheath 110 to the penis 30 such that leakage above the area where the adhesive layer 115 contacts the outer surface 32 of the penis 30 is prevented. The external urinary catheter 100 secures to the user only at the location where the adhesive layer 115 contacts the outer surface 32 of the penis. No other belts, straps, garments, or coupling/attaching devices are necessary. The catheter 100 of the present invention thereby provides a more comfortable solution to incontinence, and is not highly cumbersome or bulky for the user.

The external urinary catheter 100 can be removed from the penis 30 by pulling the upper portion 150 of the tubular sheath 110 away from the penis 30 and down over the outer surface 114. Removal can be accomplished in any manner that accommodates the comfort of the patient. It will be appreciated that one appropriate method of removing the catheter 100 is to roll the upper portion 150 up again so that the catheter 100 returns to generally the same orientation as that shown in FIG. 1. When removing the catheter 100, the adhesive layer 115 releases the outer surface of the penis 30, and the catheter 100 can be removed from the penis 30 with relative ease.

Generally speaking, the external urinary catheter 100 can be worn for variable amounts of time depending on the user, the capacity for which the device is designed, and the amount of urinary discharge the user is experiencing. For example, the external urinary catheter 100 can be worn for certain defined periods of time, until the catheter begins to feel uncomfortable, until the absorbent has reached an absorbance capacity, or until the user removes the catheter to void.

Depending on the specific absorbent material 120 utilized, the catheter 100 may exhibit altered characteristics when the

material has absorbed an amount of urine. Examples of such altered characteristics include an increase in the weight of the catheter 100 and a change in the flexibility of the portion of the catheter 100 that contains the absorbent material 120. In certain embodiments, the absorbent material can change color to indicate that material is saturated with urine. Changes such as these and others can also be used by the wearer to determine when the catheter 100 should be removed and/or replaced.

In addition, in embodiments having a detachable receptacle 122 (e.g., FIG. 24), the tubular sheath 110 can be worn throughout the day, not only between voiding. In particular, the receptacle 122 can be detached when the user needs to void. The user can then void through the open end 166 of the tubular sheath 110, and then reattach the receptacle 122 or reattach a replacement receptacle to the same tubular sheath 110.

## III. Method of Manufacturing

As described herein below, the tubular sheath 110 can be made by combining two or more layers of a silicone rubber solution or of separate silicone rubber solutions. Once the silicone rubber solutions are dried and cured in a vulcanizing process, the respective silicone rubber solution coatings combine to form a single unitary tubular sheath without separate layers. It will be appreciated that any silicone rubber solution used to form silicone rubber products of one type or another may be used to form the silicone rubber sheath of the present invention. The vulcanizing process may be either a heat process, a catalyzed process employing a catalyzing agent or agents, a combination of the two, or any other suitable vulcanizing process known in the art.

Referring now to FIGS. 15-22, a suitable method of making an external urinary catheter 100 of the present invention includes a series of steps designed to coat a mandrel 20. The mandrel 20 has a generally cylindrical shape, which may narrow or taper at a lower end 22 (FIG. 15). In one embodiment, the lower end 22 of mandrel 20 may include a larger diameter than that of the remaining mandrel 20. The mandrel 20 having a larger lower end diameter may be utilized to form a bulbous portion 162 at the distal end 116 of the tubular sheath 110, such as shown in FIG. 4. Alternatively, the lower end 22 of mandrel 20 may be configured to provide the embodiments shown in FIGS. 2, 3, and 5. In certain embodiments, either the external surfaces 164 of the mandrel 20 are coated with Teflon®, or the mandrel 20 is made of Teflon®. A tip (not shown) for forming male or female connectors 158, 160 (FIGS. 6 and 7) of the joining assembly 124 can be coupled to the lower end 22 of the mandrel 20.

In an embodiment, depicted in FIG. 22, a series of mandrels 20 are attached to a pallet 23 so that numerous external urinary catheters 100 can be mass-produced. This can be accomplished by coating each of the mandrels 20 in a series of coating steps. The coating steps include dipping each of the mandrels 20, e.g., in unison, in a series of dip tanks 80a-e that are raised up to a precise level calculated to accomplish a specific task. It will be appreciated that a series (not shown) of pallets can also be employed so that a continuous mechanized production operation can be developed to mass-produce catheters 100. The pallet 23 or a series of pallets (not shown) are advanced by a mechanized advancing system 88. It will be appreciated that any known mechanization system for advancing the pallet 23 or pallets can be used.

Referring now to FIGS. 16 and 22, in one method of manufacture, a first portion 24 of the mandrel 20 is coated with a silicone coating 40. The first portion 24 of the mandrel 20 is defined as the area of the mandrel between dashed lines A and B illustrated in FIG. 16. To create the silicone coating 40, the

## 11

pallet **23** of mandrels **20** is dipped into a first dip tank **80a** containing a fluid silicone release agent **81**, e.g., a polydimethylsiloxane fluid (Dow Corning 360 Medical Fluid from Dow Corning, Inc., Midland, Mich. 48360) having a viscosity of 12,500 centistokes, diluted about 1:25 in hexamethyldisiloxane. The fluid silicone release agent **81** forms the silicone coating **40**. In order to ensure that the first portion **24** (FIGS. **16-18**) of the mandrel **20** is completely coated with the silicone coating **40**, the pallet **23** to which the mandrels **20** are attached is centered over the first dip tank **80a** and the dip tank **80a** is raised a calculated distance, as shown. The distance is calculated such that the mandrel **20** is submersed within the release agent **81** to a designated level corresponding to the dashed line A. At the designated level, the entire first portion **24** of mandrel **20** is submersed. After the first portion **24** is fully submersed, the first dip tank **80a** is lowered and the silicone coating **40** is permitted to dry (FIG. **16**).

Referring now to FIGS. **17** and **22**, the pallet **23** is then advanced to a second dip tank **80b** containing adhesive material or fluid **82**. The adhesive material **82** bonds to unvulcanized silicone rubber during a vulcanizing process. The adhesive material **82** can include a suitable polymeric adhesive, such as a suitable copolymer of acrylic acid esters with vinylacetate, or cross linking pressure sensitive adhesive, for instance. One example of an adhesive that can be used is Gelva MAS 788 manufacture by Solutia Inc. (St. Louis Mo.). The second dip tank **80b** is raised a distance (not shown) calculated to dip the mandrel **20** into the adhesive fluid **84** in the second dip tank **80b** so that the entire first portion **24** of the mandrel **20** between the lines designated A and B is coated by the adhesive fluid **82**. As shown in FIG. **17**, the adhesive fluid **82** forms the adhesive layer **115**, which is disposed over the silicone coating **40**. The second dip tank **80b** is then lowered, and the adhesive layer **115** allowed to dry for a period of time.

Referring now to FIGS. **18** and **22**, the pallet **23** is then advanced to a third dip tank **80c** containing a solvent **83**, e.g., trichloroethane (trichlor 1,1,1) or xylene. The solvent **83** strips or removes the adhesive layer **115** and the silicone coating **40** from the mandrel **20**. In this step, the dip tank **80c** is raised a distance (not shown) calculated to dip the mandrel **20** into the solvent **83** up to the line on the mandrel **20** designated B so that the adhesive layer **115** and the silicone fluid coating **40** which coat a second portion **26** of the mandrel **20** is stripped. The second portion **26** of the mandrel **20** is defined as the area of the mandrel below the line designated B, and proximate the lower end **22** of the mandrel **20**. In some methods, the tank **80c** may be lowered and raised several times to provide a rapid stripping action. The pallet **23** can also be advanced to a new dip tank (not shown) having a second solvent (not shown) to further assist in stripping the second portion **26** of the mandrel **20**. In some embodiments, a vibrator (not shown) is connected to the pallet **23** or the mandrel **20** to vibrate the mandrel **20** and speed the removal of the adhesive coating **115**. In other embodiments, an ultrasonic cleaning system (not shown) is incorporated into the dip tank **80c**.

In some methods, a further step can be added at this point in the manufacturing process. This step involves shaping the lower end **22** of mandrel **20** by selectively coating the lower end **22** with an agent that buildups the lower end **22**. Shaping the lower end **22** of the mandrel **20** provides the shaped distal end **116** configurations of the catheter **100** previously disclosed. The agent can be the same or similar to that of the mandrel release agent **81** utilized previously.

In continuing the manufacture of the catheter **100**, the mandrel **20** is advanced on the pallet **23** to a fourth dip tank **80d** containing an unvulcanized silicone rubber solution **84**

## 12

which can be a disiloxane solvent, e.g., a hexamethyldisiloxane solvent. The disiloxane solvent is suitable because the disiloxane solvent does not destroy the integrity of the adhesive layer **1715** that remains on the first portion **24** of the mandrel **20**. When the mandrel **20** is dipped into the silicone rubber solution **84** in the fourth dip tank **80d**, the silicone rubber solution **84** coats the mandrel **20** and overcoats the silicone coating **40** and the adhesive layer **115**. This overcoating forms a first overcoat layer **46** as shown in FIG. **19**. If the shaping step was performed, the first overcoat layer **46** will have a shaped region, such as an enlarged region, that eventually becomes the distal end **116** of the tubular sheath **110**. The fourth dip tank **80d** is then lowered, and the overcoat layer **46** is allowed to dry for a period of time.

Referring now to FIGS. **20** and **22**, the pallet **23** is then advanced to a fifth dip tank **80e** containing an additional silicone rubber solution **85**. The additional silicone rubber solution **85** can have a greater concentration of silicone rubber than the first overcoat layer **46**. The solvent may also be varied. The dip tank **80e** is raised and the mandrel **20** is dipped into the dip tank **80e** to a level just below the line designated B so as to add an additional thickness proximate the lower end **22** of the mandrel **20**. This forms a final overcoat layer **48** over the first overcoat layer **46**. The dip tank **80e** is then lowered and the final overcoat layer **48** is allowed to air dry so that the solvent in the silicone rubber overcoat layer **48** evaporates. It will be appreciated that additional dip tanks may be provided for additional dipping steps.

In one embodiment, the first overcoat layer **46** has a generally uniform thickness through out the construction of the sheath **110**. The thickness is typically between about 0.002 and 0.010 inches; e.g., between about 0.003 and 0.008 inches. The final overcoat layer **48** provides additional thickness in the proximal region **116** of the sheath **110**. The thickness at the distal end **116** is between 0.020 to 0.080 inches; e.g., between about 0.030 to 0.060 inches.

In an embodiment of the method, the final overcoat layer **48** is vulcanized or cured in an oven (not shown) at an elevated temperature, e.g., about 205° F. It will be appreciated that the temperature is maintained at a level below the boiling point of the solvents of the silicone rubber solutions to prevent the formation of bubbles in the silicone rubber caused by evaporation or the boiling off of the solvents. Furthermore, it will also be appreciated that other silicone rubber systems that are catalyzed without heat may also be used to provide a vulcanizing system resulting in a vulcanized silicone rubber elastomeric construction **50**.

Once the silicone rubber has been vulcanized, the tubular sheath **110** is formed. The tubular sheath **110** is permitted to cool. When cooled, the upper portion **150** of the tubular sheath is rolled from a top **25** of the mandrel **20** (FIG. **21**) so that the inner surface **112** (FIG. **23**) of the tubular sheath **110** rolls up onto the outer surface **114** of the tubular sheath. In the process of rolling the tubular sheath **110**, the adhesive layer **115**, which has now been integrally bonded with the silicone rubber during the vulcanizing process, comes into contact with the outer surface **114** of the tubular sheath **110**.

Referring to FIG. **23**, when the catheter **100** is fully rolled up into its pre-use orientation (as shown in FIG. **1**), the catheter **100** includes the single tubular sheath **110** (FIG. **1**) having a unitary construction made of silicone rubber with an adhesive layer **115** integrally bonded to the tubular sheath **110**. The adhesive layer **115** is interposed between the inner surface **112** and the outer surface **114** of the sheath **110**. The adhesive layer **115** is integrally bonded to the inner surface **112** as a result of cross-linking between constituents in the adhesive layer **115** and constituents in the unvulcanized sili-

## 13

cone rubber of the overcoat layer **46** during the vulcanizing process. The adhesive layer **115** will not, however, irreversibly adhere or bond to any of the vulcanized silicone rubber surfaces with which the adhesive contacts after the vulcanizing process. The adhesive layer **115** does contact the outer surface **114**, but any adherence to the outer surface **114** is limited to releasable adherence.

In particular, when the upper portion **150** of the tubular sheath is rolled up, trace amounts of the silicone coating **40** adhere to the adhesive layer **115**, and the remaining portion of the silicone coating **40** stays on the mandrel **20**. The trace amounts of silicone coating **40** that adhere to the adhesive strip are absorbed by the outer surface **114** of the tubular sheath **110** when the coating **40** comes into contact with the outer surface **114**.

It is to be appreciated that it is important that the trace amounts of silicone fluid adhering to the adhesive layer **115** are absorbed by the outer surface **114**, because if not absorbed, the coating **40** could interfere with the adherence of the adhesive layer **115** with the penis **30**. It will also be appreciated that the silicone coating **40** is just one of many mandrel release agents which can be used to coat the mandrel **20**. Other agents that prevent making removal of the adhesive layer **115** from the mandrel **20** overly difficult can also be used.

The adhesive layer **115** is selected for its ability to bond with the silicone rubber during the vulcanized process and for its lack of adherence when the layer **115** comes into contact with vulcanized silicone rubber after the vulcanizing process. It will be appreciated that any biocompatible adhesive which will cross-link with silicone rubber during the vulcanizing process will be a suitable adhesive so long as the biocompatible adhesive will releasably adhere to new silicone rubber surfaces with which the biocompatible adhesive comes into contact after the adhesive is bonded to the inner surface of a silicone rubber sheath during the vulcanizing process.

Inclusion of the absorbent material **120** occurs after the above formation of the tubular sheath **110**. The specific method of providing or including the absorbent material **120** depends on the specific type of the absorbent material **120** used, and the specific arrangement. For example, in the embodiments having the absorbent material **120** located in the distal end **116** of the sheath **110**, the absorbent material **12** is typically placed at or adjacent to an enclosed tip **53** (FIG. **21**) of the sheath **110**. For instance, if the absorbent material **120** is hydrophilic powder, the material can simply be introduced into the tubular sheath **110**, and directed towards the enclosed tip **53** at the distal end **116** of the sheath **110**. If the hydrophilic powder is to be adhered to the inner surface **112** of the tubular sheath **110**, a suitable adhesive, such as Gelva Mas 788, for example, can be applied to the desired portion of the tubular sheath **110** adjacent the enclosed tip **53** before the powder is introduced into the tubular sheath **110**.

In the embodiments having the absorbent material **120** located in the receptacle **122**, the enclosed tip **53** of the tubular sheath **110** is removed to provide the opening **166** (FIG. **24**) at the distal end **116**. The absorbent material **12** is disposed in the receptacle **122**, and the receptacle is interconnected to the opening **166** at the distal end **116** via the joining assembly **124**.

The above specification provides a complete description of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, certain aspects of the invention reside in the claims hereinafter appended.

## 14

We claim:

1. An external urinary catheter, comprising:
  - a tubular sheath of silicone rubber, the tubular sheath having an inner surface and an outer surface;
  - a layer of adhesive material for securing the tubular sheath to a user at a location during use, the layer of adhesive material being non-releasably bonded to a portion of the inner surface of the tubular sheath;
  - a receptacle detachably interconnected to a distal end of the tubular sheath, the receptacle defining an interior in which urinary discharge is collected; and
  - an absorbent material disposed within the interior of the receptacle to absorb the urinary discharge, the absorbent material being contained within and surrounded by a semipermeable coverstock;
 wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath, and wherein the receptacle is sized such that the receptacle resides within a user's pelvic region when the catheter is worn.
2. The catheter of claim 1, wherein the absorbent material includes cellulose fiber.
3. The catheter of claim 1, further including a joining assembly positioned between the distal end of the tubular sheath and the receptacle, the joining assembly providing fluid communication between the tubular sheath and the receptacle.
4. The catheter of claim 3, wherein the joining assembly is detachably interconnected to the distal end of the tubular sheath.
5. The catheter of claim 3, wherein the joining assembly includes a fitting sized for receipt within an opening formed in the distal end of the tubular sheath, the fitting and receptacle being detachable from the opening of the tubular sheath.
6. The catheter of claim 1, wherein the interior volume of the receptacle is sized to collect no more than 100 mL of urine.
7. The catheter of claim 1, wherein the interior volume of the receptacle is between about 1.0 and 5.0 cubic inches.
8. The catheter of claim 1, wherein the receptacle has a width and a height, the width being between about 2.0 and 3.0 inches, and the height being between about 3.0 and 4.0 inches.
9. The catheter of claim 1, wherein the catheter secures to the user only at the location contacted by the layer of adhesive material.
10. The catheter of claim 1, wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.
11. The catheter of claim 1, wherein a packet comprises the semi-permeable coverstock and the absorbent material.
12. An external urinary catheter, comprising:
  - a tubular sheath of silicone rubber, the tubular sheath having an inner surface and
  - an outer surface, the tubular sheath further having a main portion and a bulbous distal end, the main portion being sized to receive an user's penis, the bulbous distal end being greater in diameter than the main portion of the tubular sheath;
  - a layer of adhesive material that secures the tubular sheath to the user's penis at a location during use, the layer of



15

adhesive material being non-releasably bonded to a portion of the inner surface of the tubular sheath; and an absorbent material disposed in the bulbous distal end of the tubular sheath to absorb urinary discharge, the absorbent material being contained within and surrounded by a semipermeable coverstock;

wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath, and wherein the entire external urinary catheter resides within a user's pelvic region when the catheter is worn.

13. catheter of claim 12 wherein the absorbent material includes cellulose fiber.

14. The catheter of claim 12 wherein the tubular sheath includes a necked portion located between the main portion and the bulbous distal end.

15. The catheter of claim 12 wherein the catheter secures to the user only at the location contacted by the layer of adhesive material.

16. The catheter of claim 12, wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.

17. The catheter of claim 12, wherein a packet comprises the semi-permeable coverstock and the absorbent material.

18. An external urinary catheter, comprising:  
a tubular sheath of silicone rubber, the tubular sheath having an inner surface and an outer surface;

a layer of adhesive material for securing the tubular sheath to a user at a location during use, the layer of adhesive material being non-releasably bonded to a portion of the inner surface of the tubular sheath;

an absorbent material disposed in relation to the tubular sheath to absorb urinary discharge, the absorbent material being contained within and surrounded by a semi-permeable coverstock; and

wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath.

19. The catheter of claim 18 wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and

16

prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.

20. The catheter of claim 18 wherein the tubular sheath has a main portion and a distal end, the absorbent material being disposed in the distal end of the tubular sheath.

21. The catheter of claim 18 further including a receptacle attached to the distal end of the tubular sheath, the absorbent material being disposed within the receptacle.

22. The catheter of claim 18, wherein a packet comprises the semi-permeable coverstock and the absorbent material.

23. An external urinary catheter, comprising:  
a tubular sheath of silicone rubber, the tubular sheath having an inner surface and an outer surface;

a layer of adhesive material for securing the tubular sheath to a user at a location during use;

a receptacle detachably interconnected to a distal end of the tubular sheath by a joining assembly, the receptacle defining an interior in which urinary discharge is collected, the receptacle residing within a user's pelvic region when the catheter is worn, the joining assembly including a fitting received within an opening formed in a distal end of the tubular sheath; and

an absorbent material disposed within the interior of the receptacle to absorb the urinary discharge, the absorbent material being contained within and surrounded by a semipermeable coverstock.

24. The catheter of claim 23, wherein the fitting has a tapered end that is received within the opening of the tubular sheath.

25. The catheter of claim 23, wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath.

26. The catheter of claim 23, wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.

27. The catheter of claim 23, wherein a packet comprises the semi-permeable coverstock and the absorbent material.

\* \* \* \* \*